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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2022

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-36833

VOLITIONRX LIMITED

(Exact name of registrant as specified in its charter)

Delaware	**91-1949078**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1489 West Warm Springs Road, Suite 110
Henderson, Nevada 89014
(Address of principal executive offices)

+1 (646) 650–1351
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s):	Name of Each Exchange on Which Registered:
Common Stock, par value $0.001 per share	**VNRX**	**NYSE American, LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes☐ No ☒

As of June 30, 2022, the last trading day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting common stock held by non-affiliates of the registrant was $73,353,231 (based upon the $2.05 per share closing price for the registrant's common stock as reported by the NYSE American on such date). This calculation does not reflect a determination that persons deemed to be affiliates for this purpose are affiliates for any other purpose.

As of March 8, 2023, there were 63,096,766 shares of the registrant's $0.001 par value common stock issued and outstanding.

Documents incorporated by reference:

Portions of the registrant's definitive Proxy Statement on Schedule 14A for its 2023 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission on or before May 1, 2023 are incorporated by reference into Part III, Items 10-14 of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2022, (this "Report"), and the information and documents incorporated by reference in this Report, contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which statements are subject to considerable risks and uncertainties. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact included in this Report or incorporated by reference into this Report are forward-looking statements. We have attempted to identify forward-looking statements by using words such as "aim," "anticipate," "believe," "continue," "could," "estimate(s)," "expect," "forecast(s)," "goal," "intend," "may," "plan(s)," "potential," "project," "seek," "should," "strategy," "will," and other forms of these words or similar words or expressions or the negative thereof (although not all forward-looking statements contain these words). In particular, forward-looking statements contained in this Report, and the information and documents incorporated by reference within this Report, relate to, among other things, our predictions of earnings, revenues, expenses or other financial items; plans or expectations with respect to our development activities or business strategy, including regulatory approvals, commercialization and market acceptance; statements concerning industry trends and industry size; statements regarding anticipated demand for our products and market opportunity, or the products of our competitors; statements relating to manufacturing forecasts, and the potential impact of our relationships with contract manufacturers, original equipment manufacturers and distributors on our business; assumptions regarding the future cost and potential benefits of our research and development efforts; the effect of critical accounting policies; forecasts of our liquidity position or available cash resource and financing plans; and statements relating to the assumptions underlying any of the foregoing. We caution you that the foregoing list may not include all of the forward-looking statements made in this Report and the information and documents incorporated by reference within this Report.

We have based our forward-looking statements on our current assumptions, expectations and projections about trends affecting our business and industry and other future events. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. Forward-looking statements are subject to substantial known and unknown risks and uncertainties that could cause our future business, financial condition, results of operations or performance to differ materially from our historical results or those expressed or implied in any forward-looking statement contained in this Report.

Some significant factors that may impact our estimates and forward-looking statements include, but are not limited to:

- *Our inability to generate any significant revenue or achieve profitability;*
- *Our need to raise additional capital in the future;*
- *Our expectations to expand our product development, research and sales and marketing capabilities could give rise to difficulties in managing our growth;*
- *Our limited experience with direct sales and marketing;*
- *The material weaknesses in our internal control over financial reporting that we have identified;*
- *The possibility that we may not be able to continue to operate, as indicated by the "going concern" opinion from our auditors;*
- *Our ability to successfully develop, manufacture, market, and sell our future products;*
- *Our ability to timely obtain necessary regulatory clearances or approvals to distribute and market our future products;*
- *The acceptance by the marketplace of our future products;*
- *The highly competitive and rapidly changing nature of the diagnostics market;*
- *Our reliance on third parties to manufacture and supply our intended products, and such manufacturers' dependence on third party suppliers;*
- *Our dependence on third party distributors;*
- *Protection of our patents, intellectual property and trade secrets; and*
- *Business disruptions and economic and other uncertainties surrounding the COVID-19 pandemic.*

For additional information, refer to the section entitled "Risk Factors" in Part I, Item 1A of this Report, and the other documents that we have filed with the U.S. Securities and Exchange Commission (the "SEC").

In addition, actual results may differ as a result of additional risks and uncertainties of which we are currently unaware or which we do not currently view as material to our business. For these reasons, readers are cautioned not to place undue reliance on any forward-looking statements.

You should read this Report in its entirety, including the documents that we file as exhibits to this Report and the documents we incorporate by reference into this Report, with the understanding that our future results may be materially different from what we currently expect. The forward-looking statements we make speak only as of the date on which they are made. We expressly disclaim any intent or obligation to update any forward-looking statements after the date hereof to conform such statements to actual results or to changes in our opinions or expectations. If we do update or correct any forward-looking statements, readers should not conclude that we will make additional updates or corrections.

Use of Terms

Except as otherwise indicated by the context, references in this Report to "Company," "VolitionRx," "Volition," "we," "us," and "our" are references to VolitionRx Limited and its wholly owned subsidiaries, Singapore Volition Pte. Limited, Belgian Volition SRL, Volition Diagnostics UK Limited, Volition Germany GmbH, Volition America, Inc, and Volition Global Services SRL, as well as majority owned subsidiary Volition Veterinary Diagnostics Development LLC. Additionally, unless otherwise specified, all references to "$" refer to the legal currency of the United States of America.

Nucleosomics™ and Nu.Q® and their respective logos are trademarks and/or service marks of VolitionRx and its subsidiaries. All other trademarks, service marks and trade names referred to in this Report are the property of their respective owners.

PART I

ITEM 1. BUSINESS

Overview

Volition is a multi-national epigenetics company powered by Nu.Q®, its proprietary nucleosome quantification platform. Through its subsidiaries, Volition is developing simple, easy to use, cost effective blood tests to help diagnose and monitor a range of life-altering diseases including some cancers and diseases associated with NETosis such as sepsis and COVID-19. Early diagnosis and monitoring have the potential to not only prolong the life of patients but also improve their quality of life. The tests are based on the science of Nucleosomics™, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid - an indication that disease is present.

We have five key pillars of focus, all of which use the same proprietary Nu.Q® platform to commercialize in different areas:

- **Nu.Q® Vet -** cost-effective, easy-to-use cancer screening blood test for dogs and other animals.
- **Nu.Q® NETs -** monitoring the immune system to save lives.
- **Nu.Q® Cancer -** detecting cancer early to save lives.
- **Nu.Q® Capture -** capturing and concentrating samples for more accurate diagnosis.
- **Nu.Q® Discover -** a complete solution to profiling nucleosomes.

Our product development and manufacturing activities are centered in Belgium, with innovation and U.S. operations in California, and additional offices in Nevada, London, and Singapore, where we focus on bringing our diagnostic and disease monitoring products to market.

Volition's Solution and the Science Behind It

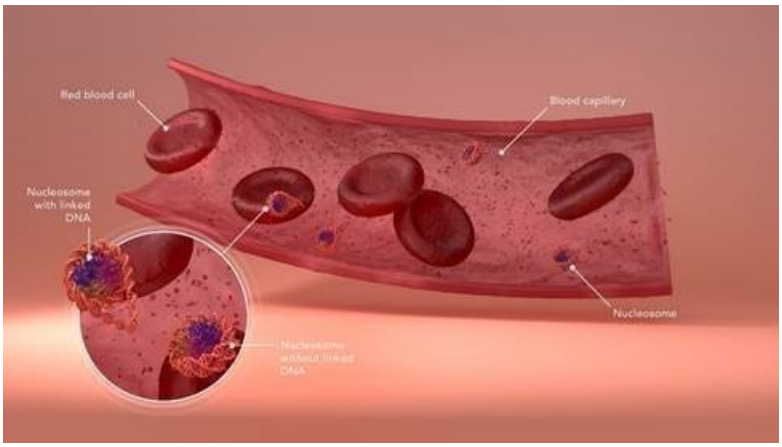
We are dedicated to revolutionizing the diagnosis and monitoring of life-altering diseases by advancing the science of epigenetics. Imagine a world where diseases like cancer and sepsis can be diagnosed early and monitored easily using routine blood tests. That's the world we're trying to build by developing our innovative family of simple, easy to use, cost-effective Nu.Q® tests.

Our patented Nucleosomics™ technology uses chromosomal structures called nucleosomes as biomarkers in cancer and other diseases: as explained below, chromosomes consist of the genetic material (DNA) wrapped in a coat of proteins and other molecules. All the tests in our portfolio detect various characteristic changes in nucleosomes that occur from the earliest stages of disease, potentially enabling early detection and a better way to monitor disease progression and the patient's response to treatment.

Unlocking Epigenetics

We believe epigenetics is the most exciting field in disease detection and management today. Modern genetics - the study of genes and heredity, is underpinned by the linear sequences of molecular "letters" present in the DNA double helix of each living cell, many of which encode the genes. It has had an enormous impact on the practice of medicine, revolutionizing the way doctors identify people with inherited conditions, diagnose cancer, and, increasingly, design personalized treatment plans. However, there's more to chromosomes than just the DNA sequence; at Volition, we focus on chromosomes' second epigenetic code, which contains a wealth of additional information about the health and function of the body's cells. You can think of the DNA sequence of each cell as the text of an instruction manual, and epigenetics as the formatting. Some parts of the manual are bolded, highlighted, or underlined, telling the cell to emphasize those sections, while others are struck out, telling the cell to ignore those genes.

The cells of most bodily organs are continuously replaced by new ones. As they die, many old cells release their nucleosomes into the bloodstream. Our patented Nucleosomics™ technology isolates these circulating nucleosomes from the blood for quantification and analysis.



Chromosome and nucleosome structure represent a major mechanism for epigenetic control. Each chromosome contains one long, single molecule of DNA that is coated by a complex array of proteins, mostly in the form of nucleosomes, giving the stretched-out, unwound DNA/protein core, or chromatin, the appearance of "beads on a string." Unwound chromatin is accessible for reading (or transcribing) and unwound genes may be active. However, genes with coiled or supercoiled nucleosomes are inaccessible and inactive.

Each nucleosome consists of a disc of eight histone proteins wrapped by a short length of DNA. Nucleosome structure has a dual role: first, it allows the compact storage and protection of the genetic material (or DNA), and second, it modulates the epigenetic regulation (transcription) of that DNA. This regulation is achieved through reversible chemical changes to both the DNA and protein components as well as through the binding of specific regulatory proteins to the DNA.

Volition's Epigenetic Approach

Through our Nu.Q® (short for nucleosome quantification) family of tests in our five key pillars of focus, we aim to offer a new, convenient and cost-effective approach to the detection, diagnosis and monitoring of diverse diseases from a simple blood test.

Highlighting abnormalities

Our technology seeks to detect characteristic epigenetic changes in nucleosomes that occur from the earliest stages of cancer and other diseases. Epigenetic changes often occur before the diseased cells themselves become abnormal enough to show up in traditional biopsies, and oftentimes before the first symptoms are felt. We aim to replace unpleasant, invasive, and often expensive screening and diagnostic tests such as colonoscopies and biopsies with Nu.Q® blood tests, helping to save lives and to reduce overall healthcare costs.

We have five key pillars of focus: Nu.Q® Vet, Nu.Q® NETs, Nu.Q® Cancer, Nu.Q® Capture and Nu.Q® Discover, all of which use the same proprietary Nu.Q® platform to commercialize in different areas.

Nu.Q® Vet

Cancer is the most common cause of death in dogs over the age of two years in the United States. Nearly 50% of all dogs over the age of 10 will develop cancer in their lifetime. With approximately 84 million pet dogs in the United States, there are an estimated six million pet dogs diagnosed with cancer each year. As with humans, earlier detection can save lives and can also improve the quality of life of the dog and its owner. Yet, as of today, there are few single assay cancer blood tests on the veterinary market. Currently, dogs suspected of having cancer are required to undergo a variety of diagnostic tests that may be expensive, time consuming, and painful for the animal. We hope to change this with the introduction of the Nu.Q® Vet Cancer Test: a simple, cost-effective, easy to use enzyme-linked immunosorbent assay ("ELISA") based screening blood test which may help streamline the diagnostic process for older or "at-risk" dogs. For example, findings from a clinical study conducted by Volition and Professor Wilson-Robles and the team at Texas A&M University, peer-reviewed and published in August 2022, reflect that Volition's Nu.Q ® Vet Cancer Test detected 76% of systemic cancers (including lymphoma, hemangiosarcoma, and histiocytic sarcoma) at 97% specificity versus control.

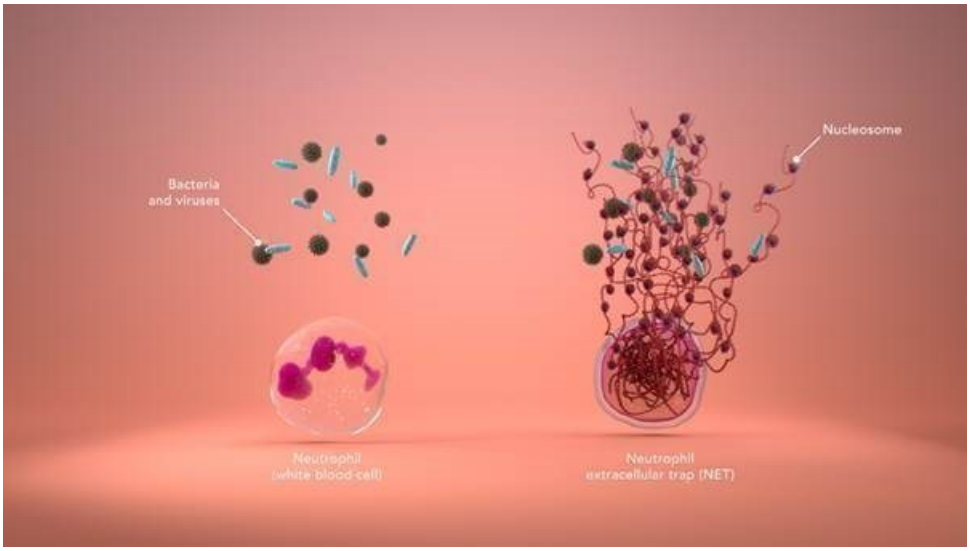
Data presented at the European Society of Veterinary Oncology Congress suggests that Nu.Q® Vet may also serve as a more sensitive measurement of both minimal residual disease and remission and could be a useful monitoring test for dogs with cancer.

We are currently conducting ongoing research regarding Nu.Q® Vet as follows:

- Point of Care platform (in partnership with the Heska Corporation),
- Broadening the range of cancers detected,
- Differential diagnosis,
- Pre-analytics for the use of Nu.Q® Vet in the feline population, and
- Use of the Nu.Q® platform in NETosis in canines.

Nu.Q® NETs - Monitoring the immune system to save lives.

The immune system can be both friend and foe; a potent protective force that sometimes overreacts, damaging the body's own cells and tissues in the process. We are working to develop tests that will identify people at high risk of poor outcomes/death caused by an immune system overreaction to sepsis, COVID-19 and other infections. The immune system is comprised of many different types of white blood cells with different functions. The most abundant of these white blood cells are neutrophils, which serve as a first line of defense. When neutrophils detect bacteria, viruses, injuries, or other threats, these cells produce Neutrophil Extracellular Traps ("NETs"), which are sticky webs made of long strings of nucleosomes that work to inhibit a perceived threat from spreading through the body.



Although NETs are an important part of the body's response to infection, the presence of too many of them in the blood can tip the immune system's delicate balance between reaction and overreaction. Elevated levels of NETs are a complicating factor associated with poor patient outcomes in a range of infectious and non-infectious diseases.

Sepsis—widespread tissue and organ damage triggered by an abnormal immune response to an infection—is an area of particular focus for our research on NETs. A recent global study estimated that there were approximately 49 million cases and 11 million sepsis-related deaths worldwide in 2017, accounting for approximately 20% of all deaths from the same year.

Severe cases of COVID-19 can cause excessive production of NETs in the lungs, which can lead to severe lung impairment or death. Because NETs contain nucleosomes, our proprietary Nu.Q® nucleosome assays have been shown to detect NETs. Using our Nu.Q® nucleosome assays could enable the stratification of patients with a high level of NETs, allow physicians to rapidly triage these patients, and monitor their disease progression and response to treatment.

In May 2022, our Nu.Q® NETs product was CE marked for the detection and evaluation of NETosis on two platforms (ELISA plates and i-10), enabling clinical use in more than 27 countries across Europe.

In August 2022, we appointed Diagnostic Oncology CRO, LLC ("DXOCRO"), a contract research organization specializing in the commercialization of diagnostic biomarker technologies, to spearhead our clinical product development and regulatory programs in the United States. DXOCRO is undertaking large-scale finding studies across multiple sites using our Nu.Q® platform to determine clinical utility in sepsis and cancer. We hope the study will support an application to the FDA's Breakthrough Device program.

The first phase of the study focused on sepsis has been completed and an application to the FDA's Breakthrough Device Program is expected to be submitted in the first half of 2023.

Nu.Q® Cancer - Detecting cancer early to save lives.

We are developing a simple, cost-effective blood test for cancer. Cancer is a devastating disease that touches many peoples' lives, accounting for approximately 10 million deaths worldwide each year. Early diagnosis is the best way to improve someone's chances of surviving cancer; however, current population-wide screening tests (such as mammograms and colonoscopies) are often invasive and unpleasant. They can also be expensive, causing many people to miss routine screening. There are no population screening tests at all for some types of cancer, including aggressive forms of the disease such as ovarian or pancreatic cancers. Unfortunately, many patients are therefore diagnosed too late, when their cancer has already spread, and treatment is more difficult. We believe that Nu.Q® Cancer can become a cost-effective routine blood test for multiple types of cancer, allowing doctors to check off an extra box along with other routine blood tests like cholesterol during an annual wellness visit. Nu.Q® Cancer tests have further potential applications in clinical oncology beyond cancer detection. Being able to use epigenetic information from tumor cells' nucleosomes could also help physicians select the best treatment for each patient, monitor their response and the disease progression.

We are currently investigating the potential use of Nu.Q® Cancer tests in a range of cancers and clinical settings.

Nu.Q® Capture - Capturing and concentrating samples for more accurate diagnosis - Locating the needle in a haystack.

Human blood is a mixture of many different cell types floating in a complex soup of proteins and other molecules, including nucleosomes released by cells from all around the body. Detecting a handful of cancerous or other abnormal cells in a patient's blood sample has historically been like finding a proverbial needle in a haystack. Volition's Nu.Q® Capture program has several strands of technology which either essentially removes background noise, thereby amplifying the signal or looks to identify the signal in a novel way. This sample enrichment tool removes healthy nucleosomes, leaving an enriched sample of abnormal nucleosomes behind for further analysis. These nucleosomes contain tumor-specific DNA "typos," epigenetic changes, and other biomarkers that when analyzed could potentially be used to diagnose a specific type of cancer or other medical condition, guide treatment selection, and monitor disease and treatment progress. Other strands of Nu.Q® Capture technology involve isolating various chromatin fragments including nucleosomes and transcription factors from plasma for analysis by mass spectrometry and next-generation DNA sequencing.

Deploying Nu.Q® Capture as the first blood sample processing step could potentially:

- Enhance the sensitivity of subsequent Nu.Q® immunoassays for diagnosing and monitoring different types of disease using our proprietary Nucleosomics™ platform,
- Aid the development of improved diagnostic DNA sequencing methods,
- Serve as a quality control tool to reduce the rate of clinical test failure, saving time that is especially valuable for people whose test results are being used to inform their treatment,
- Aid the discovery of new biomarkers, and
- Allow the complete profiling of nucleosomes.

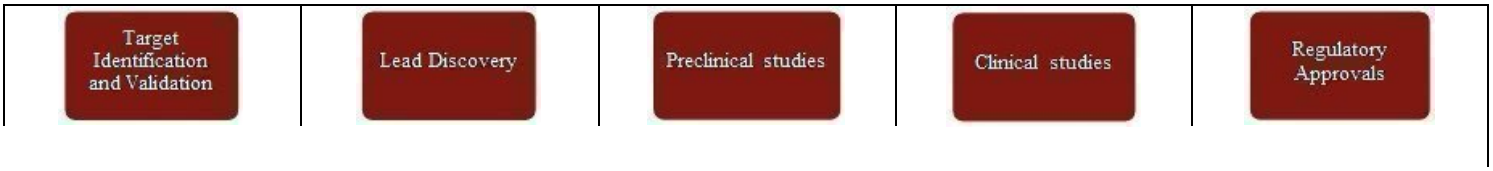
The use of Nu.Q® Capture technology in the field of transcription factors has led to the successful isolation of tumor derived transcription factor-DNA complexes from blood samples obtained from cancer patients. As transcription factor binding to DNA is cancer and tissue specific, this technology may, in principle, provide the basis for blood tests for cancer in general as well as blood tests to identify the organ or tissue affected by cancer. Development is ongoing.

Another novel method utilizing Nu.Q® Capture and mass spectrometry was published in 2021 and demonstrated the detection and quantification of histone modifications present in the circulating nucleosomes in the blood of cancer patients. We believe that our work has highlighted for the first time that histone H2A1R3 citrulline is, in plasma, upregulated in colorectal cancer patients and so could be a biomarker we target for future Nu.Q® immunoassay development. Furthermore, the use of Nu.Q® Capture may open up the possibility of using mass spectrometry not only for biomarker discovery as demonstrated in this publication but also as a high throughput platform for screening and/or diagnostics when used in combination with either sequencing and/or our Nu.Q® assays.

This technology sheds new light on epigenetic changes that cannot be effectively detected amid the noise left behind when using current testing methods, leading to better clinical tests and potentially improved outcomes in the future. Volition is engaged in multiple research collaborations with academic laboratories working at the cutting edge of their respective fields, to ensure we take advantage of the latest findings and turn them into new clinical tools as quickly as possible.

Nu.Q® Discover - A complete solution to profiling nucleosomes.

Nu.Q® Discover empowers drug developers and scientists through access to a range of state-of-the-art assays for rapid epigenetic profiling in disease, model development, preclinical testing, and clinical studies - from discovery to market ready.



Identify potential drug targets by measuring levels of specific histone modifications	**Screen and identify lead compounds** that modulate the levels of specific histone modifications	Monitor changes in histone modification levels to **assess the efficacy and Mechanism of Action (MoA) of compounds**	Monitor target engagement to determine the **pharmaco-dynamics (PD) of drugs in patients**	Support regulatory submissions and help **demonstrate drug safety and efficacy**

Manufacturing Capabilities and Strategy

Our Silver One site in Belgium offers cutting edge, purpose-built manufacturing and processing facilities. We are currently focusing on manufacturing our key components such as the antibodies and positive controls at Silver One, as well as ELISA kits. We have also outsourced a portion of the production of our ELISA kits to a third-party manufacturer in the U.S. to facilitate logistics and to aim for large-scale production.

Commercialization Strategy

We are guided by three underlying principles to our commercialization strategy – ensuring our products:

- Result in low capital expenditures for licensors and end users and low operating expenses for Volition,
- Are affordable, and
- Are accessible worldwide.

We believe, given the global prevalence of cancer and diseases associated with NETosis, and the low-cost, accessible and routine nature of our tests, Nu.Q® could potentially be used throughout the world.

We aim to remain an IP powerhouse in the Nucleosomics™ space and expect to monetize our IP and technologies through licensing and distribution contracts with companies that have established distribution networks and expertise on a worldwide or regional basis, in both human and animal care across platforms (centralized labs and point-of-care).

To this end, on March 28, 2022, Volition entered into a master license and product supply agreement with Heska Corporation ("Heska"), a leading global provider of advanced veterinary diagnostics. In exchange for granting Heska exclusive worldwide rights to sell our Nu.Q® Vet Cancer Test at the point of care for companion animals, Volition received a $10.0 million upfront payment upon signing and is eligible to receive up to an additional $18.0 million based upon the achievement of certain near and mid-term milestones. In addition, Volition has granted Heska non-exclusive rights to sell the Nu.Q® Vet Cancer Test in kit format for companion animals through Heska's network of central reference laboratories. Subsequent to year end, in February 2023 Heska commenced pre-orders of the Nu.Q® Canine Cancer Screen and Monitor Test to veterinarians at the point of care through Heska.

We also entered into a licensing and supply agreement with IDEXX Laboratories, Inc. ("IDEXX"), a global leader in pet healthcare innovation, in October 2022. This contract provides worldwide customer reach through IDEXX's global reference laboratory network as we continue to commercialize our transformational Nu.Q® technology within the companion animal healthcare sector and capitalize on the significant opportunities available. Subsequent to year end, IDEXX launched the IDEXX Canine Cancer Test in January 2023.

Further, we engaged with DNAtech, Portugal, and, through our agreement with Heska, with Scil Lab Europe, to launch the Nu.Q® Vet Cancer Test to customers in Europe commencing in November 2022.

Our Market Opportunity

Volition applies its Nucleosomics™ platform through its subsidiaries to develop simple, easy to use, cost-effective blood tests to help diagnose and monitor a range of life-altering diseases for both humans and animals including certain cancers and diseases associated with NETosis such as sepsis and COVID-19. Given the wide-ranging nature of our products in development we believe that our market opportunity is large.

Based on our calculations, we believe that Volition's annual total addressable market ("TAM") is approximately $70 billion (including distributor and vet/clinician margins). Key assumptions for this market forecast include:

- Nu.Q® Vet: opportunity is calculated based on canine and feline populations that are eligible for screening and monitoring.
- Nu.Q® Discover: opportunity is calculated using drug pipeline data (registered clinical trial programs) for relevant epigenetic targets.
- Nu.Q® NETs: opportunity is calculated based on average length of stay and estimated hospital admissions and discharges for sepsis.
- Nu.Q® Cancer: opportunity is calculated based on eligible population for annual screening, target participation rates and incidence/prevalence of specific cancers and risk stratification use cases.

We have assumed the following prices per test:

- Human: $120 for the U.S., €45 for Europe, $25 for the rest of the world.
- Veterinary: $50 globally.

To the extent that one or more of our assumptions prove incorrect our calculation could be materially impacted.

We anticipate that because of their ease of use and cost efficiency of our tests they have the potential to become the first method of choice for disease detection and monitoring in both humans and animals.

Our Competition

We anticipate facing competition primarily from other human-focused healthcare, pharmaceutical and diagnostic companies such as Exact Sciences Corporation, Guardant Health, GRAIL Inc., Freenome Holdings Inc, CellMax Life, Archer DX Inc., Foundation Medicine Inc., Oncocyte Corporation, OpKo Health Inc., MDNA Life Sciences Inc., Oncimmune Holdings Plc, Abbott Laboratories Inc., Cepheid Inc., Hologic Corporation, Agilent Technologies Inc., Qiagen Inc., Thermo Fisher, Illumina, Becton Dickinson, BioMerieux, Invitae, Siemens, Gen-Probe Incorporated, EpiGenomics AG, MDxHealth SA, and Roche Diagnostics, and from companies such as PetDx, One Health Company (Fidocure) and Vidium Animal Health focused on the veterinary space. There may also be other companies developing products competitive with ours of which we are unaware.

We predict our future products will have a competitive edge compared to those offered by competitors on the basis that our tests are developed to be accurate, cost-effective, attractive from a government reimbursement perspective, easy to use, non-invasive, technologically advanced, and compatible with immunoassay systems, based on strong intellectual property and to be used for mass screenings.

Many of our competitors have substantially greater financial, technical, and other resources and larger, more established marketing, sales and distribution systems than we have. Many of our competitors also offer broad product lines outside of the diagnostic testing market and have brand recognition. Moreover, our competitors may make rapid technological developments that may result in our intended technologies and products becoming obsolete before we are able to enter the market, recover the expenses incurred to develop them or generate significant revenue. Our success will depend, in part, on our ability to develop our intended products in a timely manner, keep our future products current with advancing technologies, achieve market acceptance of our future products, gain name recognition and a positive reputation in the healthcare industry, and establish successful marketing, sales and distribution efforts.

Government Regulations

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws and regulations have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change.

Both United States federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the federal government will continue to scrutinize, among other things, the marketing, labeling, promotion, manufacturing, and export of diagnostic healthcare products. The federal government also has increased funding in recent years to fight healthcare fraud, and various agencies, such as the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and state Medicaid fraud control units, are coordinating their enforcement efforts.

Commercialization of our future products in the clinical in vitro diagnostic (“IVD”) market (e.g. for patient diagnosis in hospitals, clinics, etc.) requires government approval (CE marking in Europe, FDA approval in the United States, and Chinese Food and Drug Administration (“CFDA”) approval in China). Our diagnostic products fall within the IVD medical device category and are subject to FDA clearance or approval in the United States. We anticipate our tests will have to be cleared through the FDA’s premarket notification (“510(k)”), process, or its premarket approval (“PMA”) process. The determination of whether a 510(k) or a PMA is necessary will depend in part on the proposed indications for use and the FDA’s assessment of the risk associated with the use of the IVD for a particular indication. A similar system operates in China through the CFDA.

In Europe, since May 2022, IVD medical devices are regulated by the new European In Vitro Diagnostic Regulation 2017/746 (“EU IVDR”). The most challenging changes compared to the previous Directive are those regarding the classification of products, which brings almost all IVDs under the direct review and control of designated assessment organizations (“Notified Bodies”), and the performance evaluation of IVDs, which requires extensive clinical and analytical performance studies in addition to a demonstration of scientific validity. Additional requirements are now applied to reinforce the safety of the products such as extended responsibilities of the economic actors of the supply chain, increased post marketing surveillance activities, unannounced audits from Notified Bodies, implementation of an improved traceability and transparency of the devices with the introduction of the Unique Device Identification system and an expanded European Database on Medical Devices.

Tailored transitional periods have been introduced for devices that must undergo a conformity assessment involving Notified Bodies for the first time under the EU IVDR. The length of the transitional periods depends on the classification of device.

In practice, the conformity assessment procedure for our products requires a combination of Quality Management System (“QMS”) audits and Technical Documentation assessments. The time needed for a Technical Documentation assessment of a device by our Notified Body (“TÜV SÜD”) is expected to last for nine months at a minimum. We have already begun discussions with the TÜV SÜD and are in the process to ensure compliance with the EU IVDR in 2023.

To support the conformity to the new IVDR, Belgian Volition has implemented a QMS, conforming to the internationally agreed standard ISO 13485 that sets out the QMS requirements specific to the medical devices industry. Belgian Volition has maintained its ISO certification since 2015.

We will also be required to comply with numerous other federal, state, and local laws relating to matters such as safe working conditions, industrial safety, and labor laws. We may incur significant costs to comply with such laws and regulations in the future, and lack of compliance could have material adverse effects on our operations.

We believe we have structured our business operations to comply with applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise, which could have a material adverse impact on our business.

Intellectual Property

Volition is developing clinical products based on the enrichment and analysis of epigenetically modified circulating nucleosomes using immunoassay, mass spectrometry, DNA sequencing and other methods. We have used this position to build a growing, broad and strong patent portfolio covering the ability to profile the epigenetic environment surrounding circulating chromosome fragments from diseased cells, including the epigenetic signaling status of nucleosomes, DNA, and other epigenetic chromatin proteins.

Our patent portfolio includes 34 patent families (plus three in-licensed families) and a total 97 patents granted related to our diagnostic tests (including veterinary applications), with 12 patents granted in the United States, 15 patents granted in Europe, and a further 70 patents granted worldwide. Additionally, we have a total of 122 patent applications currently pending, worldwide.

We intend to continue our development of the Nucleosomics™ technologies and will continue to apply for patents for future product developments. Our IP strategy is to protect the technologies and gain market exclusivity with patents in Europe and the United States and in other strategic countries. The patent filings on the technologies underlying our products should provide broad coverage for each product, including protection through at least 2043.

Employees

As of December 31, 2022, we had 104 full-time equivalent ("FTE") compared to 83 as of December 31, 2021, reflecting the growth in commercial and production activities. We continually assess employee turnover, recruitment initiatives, compensation and benefits programs, safety in performing critical laboratory work, diversity and other matters relevant to human capital management, and we review results with our board of directors on a periodic basis. We aim to offer competitive compensation (including salary, incentive bonus, and equity) and benefits packages in each of our locations and in each of our employee groups at each level around the globe as assessed with internal and external benchmarking data. We aim to build a pipeline for talent to create more opportunities for workplace diversity and to support greater representation within the Company.

Corporate History

VolitionRx Limited was originally incorporated on September 24, 1998 in the State of Delaware under the name "Standard Capital Corporation." VolitionRx acquired its wholly owned operating subsidiary, Singapore Volition Pte. Limited, a Singapore registered company ("Singapore Volition") in October 2011. Volition Global Services SRL, a Belgium private limited liability company ("Volition Global"), was formed in August 2021, which is a wholly owned operating subsidiary of VolitionRx. Singapore Volition has one subsidiary, Belgian Volition SRL, a Belgium private limited liability company ("Belgian Volition"), which it acquired in September 2010. Belgian Volition has four subsidiaries, Volition Diagnostics UK Limited, a private limited company formed under the laws of England and Wales ("Volition Diagnostics"), which was formed in November 2015, Volition America, Inc., a Delaware corporation ("Volition America"), which was formed on in February 2017, Volition Veterinary Diagnostics Development LLC, a Texas limited liability company ("Volition Vet"), which was formed in June 2019, and Volition Germany GmbH (formerly Octamer GmbH, or "Octamer" and now "Volition Germany"), a Munich, Germany-based epigenetic reagent company that it acquired in January 2020.

Our principal executive office is located at 1489 West Warm Springs Road, Suite 110, Henderson, Nevada 89014. Our telephone number is +1 (646) 650-1351. Our website is located at *www.volition.com*. The information that can be accessed through our website is not incorporated by reference into this Report and should not be considered to be a part hereof.

Financial Information

See our consolidated financial statements and accompanying notes to the consolidated financial statements included in this Report.

ITEM 1A. RISK FACTORS

Our short and long-term success is subject to numerous risks and uncertainties, many of which involve factors that are difficult to predict or beyond our control. As a result, investing in our common stock involves substantial risk. Before deciding to purchase, hold or sell our common stock, stockholders, and potential stockholders should carefully consider the risks and uncertainties described below, in addition to the other information contained in or incorporated by reference into this Report, as well as the other information we file with the SEC. If any of these risks are realized, our business, financial condition, results of operations, and prospects could be materially and adversely affected. In that case, the value of our common stock could decline, and stockholders may lose all or part of their investment. Furthermore, additional risks and uncertainties of which we are currently unaware, or which we currently consider to be immaterial, could have a material adverse effect on our business.

Certain statements made in this section constitute "forward-looking statements," which are subject to numerous risks and uncertainties including those described in this section. Refer to the section entitled "Cautionary Note Regarding Forward-Looking Statements" within this Report for additional information.

Risks Associated with Our Company

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. The summary below, as well as the discussion that follows the summary, highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important for you to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, among other things, our business may not grow, our stock price may suffer, and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial, or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations.

Risk Factor Summary

Risks Related to Our Business and Business Strategy

- We have incurred significant losses, and we may never achieve profitability.
- We may need to raise additional capital in the future. If we are unable to secure adequate funds on terms acceptable to us, we may be unable to execute our plan of operations.
- It is difficult to forecast our future performance, which may cause our financial results to fluctuate unpredictably.
- The diagnostics market is highly competitive and subject to rapid technological change; accordingly, we will face fierce competition, including from companies with greater resources and experience than us, and our intended products may not achieve significant market penetration and/or may become obsolete.
- Our management has broad discretion over the use of our available cash and might not allocate cash in ways that increase the value of your investment.
- Our future success depends on our ability to retain our officers and directors, scientists, and other key employees and to attract, retain and motivate qualified personnel.
- If any of our facilities or our laboratory equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.
- Failure in our information technology, storage systems or our clinical laboratory equipment could significantly disrupt our operations and our research and development efforts.
- Our business and reputation will suffer if we are unable to establish and comply with stringent quality standards to assure that the highest level of quality is observed in the performance of our tests.
- Declining global economic or business conditions may have a negative impact on our business.
- The COVID-19 pandemic could adversely impact our business operations, strategy, financial performance and results of operations, the extent of which is uncertain and difficult to predict.
- We may engage in acquisitions that are not successful and which could disrupt our business, cause dilution to our stockholders and reduce our financial resources.

Risks Related to Product Development, Commercialization and Sales of Our Products

- If the marketplace does not accept the products in our development pipeline or any other diagnostic products we might develop, we may be unable to generate sufficient revenue to sustain and grow our business.
- Our business is dependent on our ability to successfully develop and commercialize diagnostic products. If we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations.
- Failure to successfully develop, manufacture, market, and sell our future products will have a material adverse effect on our business, financial condition, and results of operations.
- The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials which, in turn, could have a material adverse effect on our business.
- Our research and development efforts will be hindered if we are not able to obtain samples, contract with third parties for access to samples or complete timely enrollment in future clinical trials.
- If the third parties on which we increasingly rely to assist us with our current and anticipated pre-clinical development or clinical trials do not perform as expected, we may not be able to obtain regulatory clearance or approval or commercialize our products.
- We expect to expand our product development, research and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We have limited experience with sales and marketing and any failure to build and manage a sales and marketing team effectively, or to successfully engage and maintain third party providers for such services, could have a material adverse effect on our business.
- We rely on third parties to manufacture and supply our intended products. Any problems experienced by these third parties could result in a delay or interruption in the supply of our intended products to our customers, which could have a material negative effect on our business.
- We depend on third-party distributors to market and sell our products, which will subject us to a number of risks.
- The manufacturing operations of our third-party manufacturers will likely be dependent upon third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.
- Defects in our products may subject us to substantial damages which could materially harm our business or financial condition.

Risks Related to Governmental Regulation and Reimbursement

- Our failure to obtain necessary regulatory clearances or approvals on a timely basis would significantly impair our ability to distribute and market our future products on the clinical IVD market.
- Reductions or changes in reimbursement policies could limit our ability to sell our products.
- If we are found to have violated laws concerning the privacy and security of patient health information or other personal information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

Risks Related to Our Intellectual Property

- If the patents we rely on to protect our intellectual property prove to be inadequate, our ability to successfully commercialize our products will be harmed and we may never be able to operate our business profitably.
- If third parties assert that we have infringed their patents and proprietary rights or challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and delay or prevent the development or commercialization of our products.
- If we are unable to protect our trade secrets, we may be unable to protect our interests in proprietary technology, processes and know-how that is not patentable or for which we have elected not to seek patent protection.

Risks Related to Our Securities

- The market prices and trading volume of our stock may be volatile.
- We have identified material weaknesses in our internal control over financial reporting that have not yet been remediated, and although we are working to address such weaknesses, the failure to address these material weaknesses, or the identification of any others, could impact the reliability of our financial reporting and harm investors' views of us, which could adversely impact our stock price.
- We have a "going concern" opinion from our auditors, indicating the possibility that we may not be able to continue to operate.

- Our Second Amended and Restated Certificate of Incorporation exculpates our officers and directors from certain liability to our Company and our stockholders.
- Our corporate governance documents, certain corporate laws applicable to us, and share ownership by executive officers and directors, could make a takeover attempt, which may be beneficial to our stockholders, more difficult.
- We do not expect to pay dividends in the foreseeable future.
- We may in the future issue additional shares of our common stock which would reduce investors' ownership interests in the Company, and which may cause our stock price to decline.
- Future sales of our common stock could depress the market price of our common stock.
- If equity research analysts do not publish research or reports about our business, or if they do publish such reports but issue unfavorable commentary or downgrade our common stock, the price and trading volume of our common stock could decline.
- We are a smaller reporting company and a non-accelerated filer, and we cannot be certain if the reduced disclosure requirements applicable to our filing status, as well as the exemption from the requirement to provide an auditor's attestation report regarding the effectiveness of our internal controls, will make our common stock less attractive to investors.

Risks Related to Our Business and Business Strategy

We have incurred significant losses, and we may never achieve profitability.

We are a clinical stage company and have incurred losses since our formation. As of December 31, 2022, we have an accumulated total deficit of approximately $167.3 million. As we continue the discovery and development of our future diagnostic products, we expect our expenses to increase significantly. Even as we begin to market and sell our intended products, we expect our losses to continue as a result of ongoing research and development expenses, as well as increased manufacturing, sales and marketing expenses. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict when or if we will become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and then maintain profitability, our business, financial condition and results of operations will be negatively affected, and the market value of our common stock will decline.

We may need to raise additional capital in the future. If we are unable to secure adequate funds on terms acceptable to us, we may be unable to execute our plan of operations.

We will require additional capital to fully fund our current strategic plan, which includes successfully commercializing our Nu.Q® pipeline and developing future products. If we incur delays in commencing commercialization of our Nu.Q® pipeline or other future products or in achieving significant product revenue, or if we encounter other unforeseen adverse business developments, we may exhaust our capital resources prior to the commencement of commercialization.

We cannot be certain that additional capital will be available when needed or that our actual cash requirements will not be greater than anticipated. Financing opportunities may not be available to us, or if available, may not be available on favorable terms. The availability of financing opportunities will depend on various factors, such as market conditions and our financial condition and outlook. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we are unable to obtain financing on terms favorable to us, we may be unable to execute our plan of operations and we may be required to cease or reduce development or commercialization of any future products, sell some or all of our technology or assets or merge with another entity.

It is difficult to forecast our future performance, which may cause our financial results to fluctuate unpredictably.

Our limited operating history and the rapid evolution of the market for diagnostic products make it difficult for us to predict our future performance. A number of factors, many of which are outside of our control, may contribute to fluctuations in our financial results, such as:

- our ability to develop or procure antibodies for clinical use in our future products;
- our ability to translate preliminary clinical results to larger prospective symptomatic and screening populations;
- the demand for our intended products;
- our ability to obtain any necessary financing;
- our ability to market and sell our future products;
- market acceptance of our future products and technology;
- performance of any future strategic business partners;
- our ability to obtain regulatory clearances or approvals;
- our success in collecting payments from third-party payors and customers;
- changes in technology that may render our future products uncompetitive or obsolete;
- competition with other diagnostics companies; and
- adverse changes in the healthcare industry (human and canine).

The diagnostics market is highly competitive and subject to rapid technological change; accordingly, we will face fierce competition, including from companies with greater resources and experience than us, and our intended products may not achieve significant market penetration and/or may become obsolete.

The diagnostics market is extremely competitive and characterized by rapidly evolving industry standards and new product enhancements. Our diagnostic tests are technologically innovative and require significant planning, design, development, and testing at the technological, product, and manufacturing process levels. These activities require significant capital commitments and investment. There can be no assurance that our intended products or proprietary technologies will remain competitive following the introduction of new products and technologies by competing companies within the industry. Furthermore, there can be no assurance that our competitors will not develop products that render our future products obsolete or that are more effective, accurate or can be produced at lower costs. There can be no assurance that we will be successful in the face of increasing competition from new technologies or products introduced by existing companies in the industry or by new companies entering the market.

The market for diagnostics is also significantly affected by new product introductions and other market activities of industry participants. Our competitors include large multinational corporations and their operating units, including Exact Sciences Corporation, Guardant Health, GRAIL Inc., Freenome Holdings Inc, CellMax Life, Archer DX Inc., Foundation Medicine Inc., Oncocyte Corporation, OpKo Health Inc., MDNA Life Sciences Inc., Oncimmune Holdings Plc, Abbott Laboratories Inc., Cepheid Inc., Hologic Corporation, Agilent Technologies Inc., Qiagen Inc., Thermo Fisher, Illumina, Becton Dickinson, BioMerieux, Invitae, Siemens, Gen-Probe Incorporated, EpiGenomics AG, MDxHealth SA, and Roche Diagnostics, and from companies such as PetDx, One Health Company (Fidocure) and Vidium Animal Health focused on the veterinary space. There may also be other companies developing products competitive with ours of which we are unaware. Successful commercialization of our services will require that we satisfactorily address the needs of various medical practitioners that constitute a target market to reach customers and to address potential resistance to recommendations for our services. If we are unable to continue to achieve significant market penetration, we will not be able to generate sufficient revenue to become profitable and our products may become obsolete.

Many of our competitors have greater resources and experience than us and may enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relationships with healthcare professionals, companies and consumers;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- established supply and distribution networks; and
- greater resources for product development, sales and marketing, and intellectual property protection.

Many of these other companies have developed and will continue to develop new products that will compete directly with our future products. In addition, many of our competitors spend significantly greater funds for the research, development, promotion, and sale of new and existing products. These resources may allow them to respond more quickly to new or emerging technologies and changes in consumer requirements. We also face competition in our search for third parties to assist us with sales and marketing of our product candidates, which may negatively impact our ability to enter into favorable sales and marketing arrangements. For all the foregoing reasons, we may not be able to compete successfully against our competitors, which could jeopardize our ability to recoup research and development expenditures, hurt our reputation and harm our business, results of operations and financial condition.

Our management has broad discretion over the use of our available cash and might not allocate cash in ways that increase the value of your investment

As of December 31, 2022, we had approximately $10.9 million in combined cash and cash equivalents compared to approximately $20.6 million as of December 31, 2021. Our management expects to deploy these resources primarily to expand our commercialization activities, to fund our product development efforts and for general corporate and working capital purposes. However, our management has broad discretion to pursue other objectives. Our management might not apply our cash in ways that increase or permit any return of your investment.

Our future success depends on our ability to retain our officers and directors, scientists, and other key employees and to attract, retain and motivate qualified personnel.

Our success depends on our ability to attract, retain and motivate highly qualified management and scientific personnel. In particular, we are highly dependent on Cameron Reynolds, our President and Chief Executive Officer, our other officers and directors, scientists and key employees. The loss of any of these persons or their expertise would be difficult to replace and could have a material adverse effect on our ability to achieve our business goals. In addition, the loss of the services of any one of these persons may impede the achievement of our research, development and commercialization objectives by diverting management's attention to the identification of suitable replacements, if any. There can be no assurance that we will be successful in hiring or retaining qualified personnel and our failure to do so could have a material adverse effect on our business, financial condition and results of operations.

Recruiting and retaining qualified scientific personnel and, in the future, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among pharmaceutical, biotechnology and diagnostic companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. We do not maintain "key person" insurance on any of our employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research, development and commercialization strategies. Our consultants and advisors, however, may have other commitments or employment that may limit their availability to us.

If any of our facilities or our laboratory equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

If our present, or any future facilities, were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, earthquakes, other inclement weather events or natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, it may render it difficult or impossible for us to perform our research and development for some period of time and our business could be severely disrupted. The lead time from ordering to delivery of certain specialized equipment we use can be more than six months and difficult to substitute.

Failure in our information technology, storage systems or our clinical laboratory equipment could significantly disrupt our operations and our research and development efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology ("IT") systems, which support our operations including our research and development efforts. The integrity and protection of our own data, and that of our customers, clinical trial subjects and employees, is critical to our business. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. IT systems are vulnerable to damage from a variety of sources. High-profile security breaches at other companies and in government agencies have increased in recent years, and cyber-attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclose information or unwittingly provide access to systems or data. While we devote significant resources to security measures to protect our systems and data, these measures cannot provide absolute security.

Any breach or interruption of our information technology systems could compromise our networks and the information stored therein could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, unauthorized access, loss or disclosure could also disrupt our operations, including our ability to:

- provide customer assistance services;
- conduct research and development activities;
- collect, process and prepare company financial information;
- provide information about our tests and other patient and healthcare provider education and outreach efforts through our website; and
- manage the administrative aspects of our business and damage to our reputation.

Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the U.S. Health Insurance Portability and Accountability Act of 1996, similar U.S. state data protection regulations, including the California Consumer Privacy Act, the EU's General Data Protection Regulation, and other regulations, the breach of which could result in significant penalties.

Failure to adequately protect and maintain the integrity of our information systems and data, including as a result of a security breach, may result in significant losses and have a material adverse effect on our financial position, results of operations and cash flows.

Our business and reputation will suffer if we are unable to establish and comply with stringent quality standards to assure that the highest level of quality is observed in the performance of our tests.

Inherent risks are involved in providing and marketing diagnostic and monitoring tests and related services. Patients and healthcare providers rely on us to provide accurate clinical and diagnostic information that may be used to make critical healthcare decisions. Consequently, users of our tests may have a greater sensitivity to errors than users of some other types of products and services. We must maintain high service standards and other quality controls. Performance or accuracy defects, incomplete or improper process controls, excessively slow turnaround times, unanticipated uses of our tests or mishandling of samples or test results (whether by us, patients, healthcare providers, courier delivery services, or others) can lead to adverse outcomes for patients and interruptions to our services. These events could lead to voluntary or legally mandated safety alerts relating to our tests or our laboratory facilities and could result in the removal of our products and services from the market or the suspension of our laboratories' operations. Insufficient quality controls and any resulting negative outcomes could result in significant costs and litigation, as well as negative publicity that could reduce demand for our tests and payers' willingness to cover our tests. Even if we maintain adequate controls and procedures, damaging and costly errors may occur.

Declining global economic conditions may have a negative impact on our business.

Concerns over U.S. healthcare reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries, and global inflationary pressures may contribute to increased volatility and diminished expectations for the global economy. If the economic climate deteriorates, our business, including our access to the research use only, or clinical IVD markets for diagnostic tests, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

The United Kingdom's withdrawal from the European Union became effective in January 2021. Although it is known what the terms of this withdrawal were, it is still possible that greater restrictions on imports and exports between the European Union countries and the United Kingdom and increased regulatory complexities are forthcoming. These changes may adversely affect our ability to market our future products in the United Kingdom which could have an adverse effect on our business, financial condition, and results of operations.

In addition, following Russia's military invasion of Ukraine in February 2022, NATO deployed additional military forces to Eastern Europe, and the United States, European Union, and other nations announced various sanctions against Russia. The invasion of Ukraine and the retaliatory measures that have been taken, and could be taken in future, by the U.S., NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could adversely affect our business.

The COVID-19 pandemic could adversely impact our business operations, strategy, financial performance and results of operations, the extent of which is uncertain and difficult to predict.

As a result of the COVID-19 pandemic and the related responses from government authorities, we have experienced and may continue to experience disruptions that could severely impact our business, strategy, financial performance and financial condition, as well as clinical trials, including:

- delays or difficulties in enrolling patients in clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- increased costs in our manufacturing, production and shipping processes;
- a slowdown or stoppage in the supply chain of the raw materials, components, and packaging services used to manufacture our products or our inability to secure additional or alternate sources of supplies or services needed to manufacture our products at optimal levels;
- interruptions or delays in global shipping to transport and deliver our products to our distributors and customers; and
- fluctuations in foreign currency exchange rates or interest rates resulting from market uncertainties.

The continued spread of COVID-19 has also led to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. This volatility and uncertainty may adversely affect our stock price. The actions that governments and individuals have taken in response to COVID-19 have led to a sharp contraction in many aspects of economies worldwide, including an economic slowdown, and it is possible that it could cause a global recession. If this occurs, it could negatively impact our ability to develop and commercialize our products, among other things. Even after the COVID-19 pandemic has subsided, we may continue to experience material adverse effects to our business as a result of the global economic impact of the pandemic, including local and global inflationary pressures, further or unexpected economic recessionary fears, increased political instability and threats of war, and could suffer from increased borrowing costs that limit discretionary consumer spending, which could hamper demand for our products and delay diagnostic testing and treatment.

Further, the effects of COVID-19 may exacerbate our other risk factors described in this Report. The degree to which the COVID-19 pandemic may impact our business and clinical trials and development activities will depend on future developments, which are highly uncertain, continuously evolving and cannot be predicted with confidence. Because this situation continues to evolve globally, the ultimate impacts to us of COVID-19 are uncertain, but such impacts could have a material adverse effect on our business, strategy, financial performance and financial condition.

We may engage in acquisitions that are not successful and which could disrupt our business, cause dilution to our stockholders and reduce our financial resources.

From time to time, we may consider opportunities to acquire or invest in other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or otherwise advance our business strategies. Potential and completed acquisitions and investments involve numerous risks, including the following:

- we may be unable to successfully integrate the acquired business (es) into our business;
- we may be unable to realize the anticipated benefits of the acquisition;
- the acquisition may not strengthen our competitive position; and
- our future results may suffer if we do not effectively manage our expanded operations.

We do not know if we will be able to identify future acquisitions or investments we deem suitable, whether we will be able to successfully complete any such acquisitions or investments on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies into our business. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to Product Development, Commercialization and Sales of Our Products

If the marketplace does not accept the products in our development pipeline or any other diagnostic products we might develop, we may be unable to generate sufficient revenue to sustain and grow our business.

Our intended products may never gain significant acceptance in the research or clinical marketplace and therefore may never generate substantial revenue or profits. Physicians, hospitals, clinical laboratories, researchers or others in the healthcare industry may not use our future products unless they determine that they are an effective and cost-efficient means of detecting and diagnosing cancer. If our research and studies do not satisfy providers, payors and others as to the reliability and effectiveness, we may experience reluctance or refusal on the part of the physician to use our future products. In addition, we will need to expend a significant amount of resources on marketing and educational efforts to create awareness of our future products and to encourage their acceptance and adoption. If the market for our future products does not develop sufficiently or the products are not accepted, our revenue potential will be harmed.

Our business is dependent on our ability to successfully develop and commercialize diagnostic products. If we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations.

Our current business strategy focuses on discovering, developing and commercializing diagnostic products. The success of our business will depend on our ability to fully develop and commercialize the diagnostic products in our current development pipeline as well as continue the discovery and development of other diagnostics products.

Prior to commercializing the Nu.Q® tests and other diagnostic products, we will be required to undertake time-consuming and costly development activities with uncertain outcomes, including conducting clinical studies and obtaining regulatory clearance or approval in the United States, Asia and in Europe. Delays in obtaining approvals and clearances could have material adverse effects on us and our ability to fully carry out our plan of operations. We have limited experience in taking products through these processes and there are considerable risks involved in these activities. The science and methods that we are employing are innovative and complex, and it is possible that our development programs will ultimately not yield products suitable for commercialization or government approval. Products that appear promising in early development may fail to be validated in subsequent studies, and even if we achieve positive results, we may still fail to obtain the necessary regulatory clearances or approvals. Few research and development projects result in commercial products, and perceived viability in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product, or we may be required to expend considerable resources obtaining additional clinical and nonclinical data, which would adversely impact the timing for generating potential revenue from those products. Further, our ability to develop and launch diagnostic tests is dependent on our receipt of substantial additional funding. If our discovery and development programs yield fewer commercial products than we expect, we may be unable to execute our business plan, and our business, financial condition and results of operations may be adversely affected.

Failure to successfully develop, manufacture, market, and sell our future products will have a material adverse effect on our business, financial condition, and results of operations.

We are in the process of developing a suite of diagnostic tests as well as additional products. The successful development and commercialization of our intended products is critical to our future success. Our ability to successfully develop, manufacture, market, and sell our future products is subject to a number of risks, many of which are outside our control. There can be no assurance that we will be able to develop and manufacture products in commercial quantities at acceptable costs, successfully market any products, or generate revenues from the sale of any products. Failure to achieve any of the foregoing would have a material adverse effect on our business, financial condition, and results of operations.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials which, in turn, could have a material adverse effect on our business.

We must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials. We may be required to demonstrate through large, long-term outcome trials that our product candidates are safe and effective for use in a broad population prior to obtaining regulatory approval. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, results of operations and financial condition may be adversely affected.

Our research and development efforts will be hindered if we are not able to obtain samples, contract with third parties for access to samples or complete timely enrollment in future clinical trials.

Access to human and animal sample types, such as blood is necessary for our research and product development. Acquiring samples from individuals / animals with clinical diagnoses or associated clinical outcomes through purchase or clinical studies is necessary. Lack of available samples can delay development timelines and increase costs of development. Generally, the agreements under which we gain access to human and animal samples are non-exclusive. Other companies may compete with us for access. If we are not able to negotiate access to clinical samples with research institutions, hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics and/or diagnostics on a timely basis, or at all, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed. Equally, we may not be able to conduct or complete clinical studies in a timely manner if we are unable to enroll sufficient numbers of patients in such studies, which could consequently have an adverse effect on our research and development and product commercialization efforts.

If the third parties on which we increasingly rely to assist us with our current and anticipated pre-clinical development or clinical trials do not perform as expected, we may not be able to obtain regulatory clearance or approval or commercialize our products.

As our clinical infrastructure expands, we expect to increasingly rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our current and anticipated pre-clinical investigations and clinical trials. For example, we currently rely on DXOCRO to support development and clinical validation studies for our Nu.Q® product portfolio in the United States, including by conducting large-scale finding studies across multiple sites in the U.S. using Nu.Q® NETs and Nu.Q® Cancer tests to determine clinical utility in sepsis and non-Hodgkin's lymphoma, which we hope to leverage in support of our U.S. commercialization strategy. However, if we are not able to maintain or reach mutually acceptable agreements with DXOCRO or other third parties on a timely basis, these third parties do not successfully carry out their commitments or regulatory obligations or meet expected deadlines, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to agreed-upon clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

We expect to expand our product development, research and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We are focused on developing our pipeline for future products. It is likely that our efforts will result in significant growth in the number of our consultants, advisors, and employees, in addition to the scope of our operations. For example, in connection with the anticipated commercialization of our products, we may add personnel to certain areas of our business including laboratory operations, quality assurance, and compliance. Further, as we build our commercialization efforts and expand research and development activities for new products, the scope and complexity of our operations is increasing significantly. As a result of our growth, our operating expenses and capital requirements have also increased, and we expect that they will continue to increase. Our ability to manage our growth effectively requires us to expend funds to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

We have limited experience with sales and marketing and any failure to build and manage a sales and marketing team effectively, or to successfully engage and maintain third party providers for such services, could have a material adverse effect on our business.

As an organization we have limited experience with direct sales however we are building a team of experienced individuals in terms of market intelligence, product management and account management in addition to building relationships with market-leading established distributors as commercial partners. For example, subsequent to the fiscal end year ended December 31, 2022, Heska commenced pre-order sales of our Nu.Q® Vet Cancer Test for screening and monitoring of cancer in canines to veterinarians worldwide at the point of care pursuant to our exclusive global supply and licensing agreement with Heska. We have also engaged IDEXX to make our Nu.Q® Vet Cancer Test available to reference laboratories in the United States. Although we are investing in direct marketing to support these commercial launches, we may rely on third party resources such as Heska's global network of veterinarians and IDEXX's reference laboratory network to successfully market this test and generate revenue. Any failure to build and manage a sales and marketing team effectively, or to successfully engage and maintain third-party providers for such services, could have a material adverse effect on our business.

Our products will require several dynamic and evolving sales models tailored to different worldwide markets, users and products. Our clinical sales strategy is initially focused on the clinical IVD market with the CE marking of our first product in Europe, the Nu.Q® NETs test, in May 2022. With this CE marking of our first product in Europe we intend to enter the European markets and, following the completion of any necessary regulatory clearances, certain Asian markets. Even if we receive a CE mark for a certain product, we must still seek regulatory clearance in other jurisdictions. A failure to obtain these regulatory clearances in other jurisdictions could negatively affect our business. Pending completion of our review of the regulatory environment in the United States we may decide to enter the United States market through a Clinical Laboratory Improvement Amendments ("CLIA"), certified laboratory located in the United States. We remain firmly committed to pursuing FDA approval as our primary objective. FDA approval can consist of PMA or 510(k) clearance depending on the test complexity and risk posed to patients. We intend to pursue the most appropriate approval pathway for each individual product developed. We intend to progressively grow to large volumes of tests sold to centralized laboratories and eventually reach the mass diagnostics testing market. The exact nature of the ideal sales strategy will evolve as we continue to develop our intended products and seek entry into the IVD markets.

There are significant risks involved in building and managing our sales and marketing organization, as well as identifying and negotiating deals with the right sales and distribution partners, including risks related to our ability to:

- identify appropriate partners;
- negotiate beneficial partnership and distribution agreements;
- hire qualified individuals as needed;
- generate sufficient leads within our targeted market for our sales force;
- provide adequate training for effective sales and marketing;
- protect intellectual property rights;
- retain and motivate our direct sales and marketing professionals; and
- effectively oversee geographically dispersed sales and marketing teams.

Our failure to adequately address these risks could have a material adverse effect on our ability to increase sales and use of our future products, which would cause our revenues to be lower than expected and harm our results of operations. Further, we are required to comply with numerous other federal, state, and local laws relating to matters such as safe working conditions, industrial safety, and labor laws. We may incur significant costs to comply with such laws and regulations in the future, and lack of compliance could have material adverse effects on our operations. We believe that we have structured our business operations to comply with applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise, which could have a material adverse impact on our business.

We rely on third parties to manufacture and supply our intended products. Any problems experienced by these third parties could result in a delay or interruption in the supply of our intended products to our customers, which could have a material negative effect on our business.

We rely on third parties to manufacture and supply our intended products. The manufacture of our intended diagnostic products requires specialized equipment and utilizes complicated production processes that would be difficult, time-consuming and costly to duplicate. If the operations of third-party manufacturers are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill our future sales orders. Any prolonged disruption in the operations of third-party manufacturers could have a significant negative impact on our ability to sell our future products, could harm our reputation and could cause us to seek other third-party manufacturing contracts, thereby increasing our anticipated development and commercialization costs. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards required by the FDA and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop products or receive approval of any products in a timely manner.

We depend on third-party distributors to market and sell our products, which will subject us to a number of risks.

We depend, and expect to continue to depend, on third-party distributors to market, sell, and service our products in our intended markets. For example, subsequent to the year ended December 31, 2022, Heska commenced pre-order sales of our Nu.Q® Vet Cancer Test for screening and monitoring of cancer in canines to veterinarians at the point of care and we engaged IDEXX to make our Nu.Q® Vet Cancer Test available to reference laboratories in the United States. Further, we have engaged with others including DNAtech, Portugal, and, through our agreement with Heska, with Scil Lab Europe, to launch the Nu.Q® Vet Cancer Test to customers in Europe. We are subject to a number of risks associated with reliance upon these parties and other third-party distributors including the following:

- lack of day-to-day control over the activities of third-party distributors;
- third-party distributors may not commit the necessary resources to market and sell our products to our level of expectations;
- third-party distributors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us; and
- disagreements with our distributors could result in costly and time-consuming litigation or arbitration which we could be required to conduct in jurisdictions with which we are not familiar.

If we fail to establish and maintain satisfactory relationships with our third-party distributors, our revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which could harm our results of operations and financial condition.

The manufacturing operations of our third-party manufacturers will likely be dependent upon third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

The operations of our future third-party manufacturers will likely be dependent upon third-party suppliers. A supply interruption or an increase in demand beyond a supplier's capabilities could harm the ability of our future manufacturers to manufacture our intended products until new sources of supply are identified and qualified.

Reliance on these suppliers could subject us to a number of risks that could harm our business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to suppliers prioritizing other customer orders over ours;
- damage to our brand reputation caused by defective components produced by the suppliers; and
- fluctuation in delivery by the suppliers due to changes in demand from us or their other customers.

We have implemented certain risk mitigation strategies including the diversification of suppliers by region and the internalization of certain production processes. However, any interruption in the supply of components of our future products or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our future customers, which would have an adverse effect on our business.

Defects in our products may subject us to substantial damages which could materially harm our business or financial condition.

The products we develop could lead to product liability claims based on allegations that one or more of our products contained a design or manufacturing defect which resulted in the failure to detect the disease for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

Risks Related to Governmental Regulation and Reimbursement

Our failure to obtain necessary regulatory clearances or approvals on a timely basis would significantly impair our ability to distribute and market our future products on the clinical IVD market.

We are subject to regulation by the FDA in the United States, the CE in Europe, the CFDA in China, and other regulatory bodies in other countries where we intend to sell our future products. Before we are able to place our intended products in the clinical IVD markets in the United States, China and Europe, we will be required to obtain clearance or approval of our future products from the FDA and the CFDA with respect to the United States and China, respectively, and receive a CE mark with respect to Europe. In Europe, since May 2022, IVD medical devices are regulated by the new EU IVDR. The most challenging changes under the EU IVDR as compared to the previous Directive are those regarding the classification of products, which brings almost all IVDs under the direct review and control of Notified Bodies, and the performance evaluation of IVDs, which requires extensive clinical and analytical performance studies in addition to a demonstration of scientific validity. These changes and other additional requirements to obtain a CE mark could result in delays and further expense, in terms of staff costs to us compared to the process under the previous Directive.

Additionally, even if we receive the required government clearance or approval of our intended products, we are still subject to continuing regulation and oversight. Under the FDA, diagnostics are considered medical devices and are subject to ongoing controls and regulations, including inspections, compliance with established manufacturing practices, device-tracking, record-keeping, advertising, labeling, packaging, and compliance with other standards. The process of complying with such regulations with respect to current and new products can be costly and time-consuming. Failure to comply with these regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, delays by the FDA or other regulators in granting clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators, any of which could have a material adverse effect on our business, financial condition, and results of operations. Furthermore, any FDA regulations governing our future products are subject to change at any time, which may cause delays and have material adverse effects on our operations. In Europe, IVD companies are subject to inspection for enforcement, among others things. European national agencies, such as customs authorities and/or the Departments of Health, Industry and Labor, conduct market surveillance to ensure the applicable requirements have been met for products marketed within the European Union.

Reductions or changes in reimbursement policies could limit our ability to sell our products.

Market acceptance and sales of our products will depend, in part, on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels for those products. To manage healthcare costs, many governments and third-party payers in the United States increasingly scrutinize the pricing of new products and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. We cannot be sure that reimbursement will be available for our products and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our future products.

If we are found to have violated laws concerning the privacy and security of patient health information or other personal information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of U.S. and international laws protecting the privacy and security of personal information. These laws include the U.S. Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and related regulations, U.S. state laws (such as the California Consumer Privacy Act (“CCPA”) and the California Privacy Rights Act (“CPRA”)), Canada’s Personal Information and Electronic Documents Act (“PIPEDA”) or the applicable provincial alternatives, the EU’s General Data Protection Regulation (“GDPR”), EU member states directives, or similar applicable laws. These laws place limits on how we may collect, use, share and store medical information and other personal information, and they impose obligations to protect that information against unauthorized access, use, loss, and disclosure.

If we, or any of our service providers who have access to the personal data for which we are responsible, are found to be in violation of the privacy or security requirements of HIPAA, PIPEDA, GDPR, or applicable foreign, U.S. state and Canadian provincial laws, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results. In addition, entities operating in the healthcare industry have increasingly become targets for hackers. Although we utilize a variety of measures to secure the data that we control, even compliant entities can experience security breaches or have inadvertent failures despite employing reasonable practices and safeguards.

We may also face new risks relating to data privacy and security as the United States, individual U.S. states or Canadian provinces, E.U. member states, and other international jurisdictions adopt or implement new data privacy and security laws and regulations as we continue to commercialize our products worldwide. For example, amendments to privacy and security laws (such as the CCPA and the CPRA) may impose additional requirements on us and increase our regulatory and litigation risk. As we continue to expand, our business will need to adapt to meet these and other similar legal requirements.

Risks Related to Our Intellectual Property

If the patents we rely on to protect our intellectual property prove to be inadequate, our ability to successfully commercialize our products will be harmed and we may never be able to operate our business profitably.

Our success depends, in large part, on our ability to protect proprietary methods, discoveries and technologies that we develop under the patents and intellectual property laws of the United States, Europe and other countries, so that we can seek to prevent others from unlawfully using our inventions and proprietary information. Our patent portfolio includes 34 patent families (plus three in-licensed families) and a total 97 patents granted related to our diagnostic tests (including veterinary applications), with 12 patents granted in the United States, 15 patents granted in Europe and a further 70 patents granted worldwide. Additionally, we have 122 patent applications pending, worldwide.

If we are not able to protect our proprietary technology and information, our competitors may use our inventions to develop competing products. We cannot assure you that any of the pending patent applications will result in patents being issued. In addition, due to technological changes that may affect our products or judicial interpretation of the scope of our patents, our products might not, now or in the future, be adequately covered by our patents.

If third parties assert that we have infringed their patents and proprietary rights or challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and delay or prevent the development or commercialization of our products.

Our ability to commercialize our products depends on our ability to develop, manufacture, market and sell our products without infringing the proprietary rights of third parties. Third parties may allege that our products or our methods or discoveries infringe their intellectual property rights. Numerous United States and foreign patents and pending patent applications, which are owned by third parties, exist in fields that relate to our products and our underlying methodologies, discoveries and technologies. A third party may sue us for infringing its patent rights.

Our ability to successfully commercialize our products depends on our ability to protect our proprietary technology and information. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of third-party proprietary rights. In addition, a third party may claim that we have improperly obtained or used its confidential or proprietary information. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation could divert our management's attention from other aspects of our business. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations. Additionally, we cannot be certain of the level of protection, if any that will be provided by our patents if they are challenged in court, where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license.

If we are found to infringe upon intellectual property rights of third parties, we might be forced to pay damages, potentially including triple damages. In addition to any damages, we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some or all of our products, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

If we are unable to protect our trade secrets, we may be unable to protect our interests in proprietary technology, processes and know-how that is not patentable or for which we have elected not to seek patent protection.

In addition to patented technology, we rely upon trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult or impossible to obtain or enforce. We may not be able to protect our trade secrets adequately. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our trade secrets and other proprietary technology. These agreements may be breached, and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential information into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us, which could adversely affect our competitive advantage.

Risks Related to Our Securities

The market prices and trading volume of our stock may be volatile.

The market price of our common stock is likely to be highly volatile and the trading volume may fluctuate and cause significant price variation to occur. We cannot assure you that the market prices of our common stock will not fluctuate or decline significantly in the future. Some of the factors that could negatively affect the prices of our shares or result in fluctuations in those prices or in trading volume of our common stock could include the following, many of which will be beyond our control:

- competition;
- comments by securities analysts regarding our business or prospects;
- additions or departures of key personnel;
- our ability to execute our business plan;
- issuance of common stock or other securities;
- operating results that fall below expectations;
- loss of any strategic relationship;
- industry developments;
- economic and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price and trading volume of our common stock.

We have identified material weaknesses in our internal control over financial reporting that have not yet been remediated, and although we are working to address such weaknesses, the failure to address these material weaknesses, or the identification of any others, could impact the reliability of our financial reporting and harm investors' views of us, which could adversely impact our stock price.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Exchange Act Rule 13a-15(f), internal control over financial reporting is a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and/or directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

We have determined that we have material weaknesses in our internal control over financial reporting as of December 31, 2022. See Part II, Item 9Aof this Report for a complete discussion of these material weaknesses in our internal control over financial reporting and remediation efforts. Although we have taken and continue to take steps to address these material weaknesses, the existence of a material weakness is an indication that there is more than a remote likelihood that a material misstatement of our financial statements will not be prevented or detected in the current or any future period. There can be no assurance that we will be able to fully implement our plans and controls, as further described in Item 9A, to address these material weaknesses, or that the plans and controls, if implemented, will be successful in fully remediating these material weaknesses. In addition, we may in the future identify further material weaknesses in our internal control over financial reporting that we have not discovered to date. If we fail to successfully remediate the identified material weaknesses, or we identify further material weaknesses in our internal controls, the market's confidence in our financial statements could decline and the market price of our common stock could be adversely impacted. Additionally, for so long as we remain as a smaller reporting company, under current rules our accounting firm will not be required to provide an opinion regarding our internal controls over financial reporting.

We have a "going concern" opinion from our auditors, indicating the possibility that we may not be able to continue to operate.

Our independent registered public accountants have expressed substantial doubt about our ability to continue as a going concern. This opinion could materially limit our ability to raise additional funds by issuing new debt or equity securities or otherwise. If we fail to raise sufficient capital when needed, we will not be able to complete our proposed business plan. As a result, we may have to liquidate our business and investors may lose their investments. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our plan of operations described herein, obtain financing and eventually attain profitable operations. Investors should consider our independent registered public accountant's comments when deciding whether to invest in the Company.

Our Second Amended and Restated Certificate of Incorporation exculpates our officers and directors from certain liability to our Company and our stockholders.

Our Second Amended and Restated Certificate of Incorporation contains a provision limiting the liability of our officers and directors for their acts or failures to act, except for acts involving intentional misconduct, fraud or a knowing violation of law. This limitation on liability may reduce the likelihood of derivative litigation against our officers and directors and may discourage or deter our stockholders from suing our officers and directors based upon breaches of their duties to our Company.

Our corporate governance documents, certain corporate laws applicable to us, and share ownership by executive officers and directors, could make a takeover attempt, which may be beneficial to our stockholders, more difficult.

Our board of directors has the power, under our charter documents to:

- issue additional shares of common stock without having to obtain stockholder approval for such action;
- fill vacant directorships except for vacancies created by the removal of a director;
- amend our bylaws without stockholder approval subject to certain exceptions; and
- require compliance with an advance notice procedure with regard to business to be brought by a stockholder before an annual or special meeting of stockholders and with regard to the nomination by stockholders of candidates for election as directors.

Further, our executive officers and directors beneficially own an amount of our outstanding shares of common stock such that if they were collectively to oppose a third party's acquisition proposal for, or a change in control of, the Company, such officers and directors may have sufficient voting power to be able to block or at least delay such an acquisition or change in control from taking place, even if other stockholders would support such a sale or change of control.

These provisions and circumstances may discourage potential acquisition proposals and could delay or prevent a change of control, including under circumstances in which our stockholders might otherwise receive a premium over the market price of our common stock.

We do not expect to pay dividends in the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not intend to declare dividends for the foreseeable future, as we anticipate that we will reinvest any future earnings in the development and growth of our business. Therefore, investors will not receive any funds unless they sell their common stock, and stockholders may be unable to sell their shares on favorable terms or at all. We cannot assure you of a positive return on investment or that you will not lose the entire amount of your investment in our common stock.

We may in the future issue additional shares of our common stock which would reduce investors' ownership interests in the Company, and which may cause our stock price to decline.

Our Second Amended and Restated Certificate of Incorporation authorizes the issuance of 100,000,000 shares of common stock, par value $0.001 per share. The future issuance of all or part of our remaining authorized common stock may result in substantial dilution in the percentage of our common stock held by our then existing stockholders. We may value any common stock issued in the future on an arbitrary basis. The issuance of common stock for future services or acquisitions or other corporate actions may have the effect of diluting the percentage ownership of our stockholders and, depending upon the prices at which such shares are sold or issued, on their investment in our common stock and, therefore, could have an adverse effect on any trading market for our common stock.

Future sales of our common stock could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market or the perception that large sales of our shares could occur, could cause the market price of our common stock to decline or limit our future ability to raise capital through an offering of equity securities.

If equity research analysts do not publish research or reports about our business, or if they do publish such reports but issue unfavorable commentary or downgrade our common stock, the price and trading volume of our common stock could decline.

The trading market for our common stock could be affected by whether and to what extent equity research analysts publish research or reports about us and our business. If one or more equity analysts cover us and publish research reports about our common stock, the price of our stock could decline rapidly if one or more securities analysts downgrade our stock or if those analysts' issue or offer unfavorable commentary or cease publishing reports about us. If any of these analysts ceases coverage of us, we could lose visibility in the market, which in turn could cause our common stock price or trading volume to decline and our common stock to be less liquid.

We are a smaller reporting company and a non-accelerated filer, and we cannot be certain if the reduced disclosure requirements applicable to our filing status, as well as the exemption from the requirement to provide an auditor's attestation report regarding the effectiveness of our internal controls, will make our common stock less attractive to investors.

We are a "smaller reporting company," meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than $250 million measured as of the last business day of our most recently completed second fiscal quarter. "Smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. We are also a "non-accelerated filer," meaning that we have a public float of less than $75 million measured as of the last business day of our most recently completed second fiscal quarter. As a "non-accelerated filer," we are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" and as a "non-accelerated filer" may make it harder for investors to analyze our results of operations and financial prospects and may make our common stock a less attractive investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Listed below are our current facilities as of December 31, 2022:

Location	Primary Function	Approx. Square Feet	Leased or Owned
Namur, Belgium [1]	Research and development	17,300	Owned
Namur, Belgium [2]	Manufacturing	9,688	Owned
London, UK [3]	Sales and marketing	323	Leased, expiring 2024
Triple One, Singapore [4]	Sales and marketing	192	Leased, expiring 2023
Henderson, Nevada [5]	Administration	301	Leased, expiring 2024
Carlsbad, California [6]	Research and development	6,645	Leased, expiring 2027

(1) Belgian Volition purchased property located in Namur, Belgium, in October 2016, to be used as a laboratory facility for R&D. The purchase price for the property was €1.2 million, exclusive of any closing costs.

(2) Belgian Volition purchased property located in Namur, Belgium, in December 2020, to be used as a manufacturing facility. The purchase price for the property was €0.6 million, exclusive of any closing costs.

(3) Volition Diagnostics signed a new 24-month lease for this property located at 93-95 Gloucester Place, London, W1U 6JQ, United Kingdom, commencing February 1, 2022 until January 31, 2024, at an annual rent of £64,800 GBP.

(4) Singapore Volition signed a one-year lease for this property, commencing July 1, 2022, located at 111 Somerset Road, Level 3, Triple One, Somerset, Singapore 238164, at an annual rent of SGD 67,524.

(5) Volition America signed a one-year lease for this property, commencing on April 1, 2022, located at 1489 West Warm Springs Road, Suite 110, Henderson, Nevada 89014, at an annual rent of $14,868. Volition America entered into a new one-year lease for this property, commencing April 1, 2023, at an annual rent of $16,308.

(6) Volition America signed a sixty-two month lease for this property, commencing on February 1, 2022, located at 6086 Corte Del Cedro, Carlsbad, California 92011 at an annual rent of $91,704.

ITEM 3. LEGAL PROCEEDINGS

In the ordinary course of business, we may be subject to claims, counter claims, suits and other litigation of the type that generally arise from the conduct of our business. We are not aware of any threatened or pending litigation that we expect will have a material adverse effect on our business operations, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market Information

Our common stock is traded on the NYSE American under the symbol "VNRX".

Holders

As of March 8, 2023, there were 63,096,766 shares of our common stock outstanding held by 148 holders of record, based on information provided by our transfer agent. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividends

We have not declared or paid any cash dividends on our common stock since inception and presently anticipate that all earnings, if any, will be retained for development of our business and that no dividends on our common stock will be declared in the foreseeable future. Any future dividends will be subject to the discretion of our board of directors and will depend upon, among other things, future earnings, operating and financial conditions, capital requirements, general business conditions and other pertinent facts. Therefore, there can be no assurance that any dividends on our common stock will be paid in the future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item will be set forth in our definitive proxy statement related to our 2023 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A, on or before May 1, 2023.

Recent Sales of Unregistered Securities

None.

Repurchase of Equity Securities

No equity securities were repurchased during the fourth quarter of 2022.

ITEM 6. RESERVED

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

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements in Part II within this Report. This discussion includes an analysis of our financial condition and results of operations for the years ended December 31, 2022 and 2021 and year-over-year comparisons between those periods. Certain statements made in this section constitute "forward-looking statements," which are subject to numerous risks and uncertainties including those described in this section. For additional information, refer to the section entitled "Cautionary Note Regarding Forward-Looking Statements" within this Report.

Company Overview

Volition is a multi-national epigenetics company powered by Nu.Q®, its proprietary nucleosome quantification platform. Through its subsidiaries, Volition is developing simple, easy to use, cost-effective blood tests to help diagnose and monitor a range of life-altering diseases, including some cancers and diseases associated with NETosis, such as sepsis and COVID-19. Early diagnosis and monitoring have the potential to not only prolong the life of patients, but also improve their quality of life.

The tests are based on the science of Nucleosomics™, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluids, since changes in these parameters are an indication that disease is present.

We have five key pillars of focus, all of which use the same proprietary Nu.Q® platform to commercialize in different areas.

- **Nu.Q® Vet** - cost-effective, easy-to-use cancer screening blood test for dogs and other animals.
- **Nu.Q® NETs** - monitoring the immune system to save lives.
- **Nu.Q® Cancer** - detecting cancer early to save lives.
- **Nu.Q® Capture** - capturing and concentrating samples for more accurate diagnosis.
- **Nu.Q® Discover** - a complete solution to profiling nucleosomes.

Our research, product development and manufacturing activities are centered in Belgium, with innovation and U.S. operations in California, and additional offices in Nevada, London, and Singapore, where we focus on bringing our diagnostic and disease monitoring products to market.

We have identified the specific processes and resources required to achieve the near and medium-term objectives of our business plan, including personnel, facilities, equipment, research and testing materials including antibodies and clinical samples, and the protection of intellectual property. To date, operations have proceeded satisfactorily in relation to our business plan. However, it is possible that some resources will not readily become available in a suitable form or on a timely basis or at an acceptable cost. It is also possible that the results of some processes may not be as expected, and that modifications of procedures and materials may be required. Such events could result in delays to the achievement of the near and medium-term objectives of our business plan, in particular the progression of clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market.

Our future as an operating business will depend on our ability to obtain sufficient capital contributions, financing and/or generate revenues as may be required to sustain our operations. Management plans to address the above as needed by: (a) securing additional grant funds; (b) obtaining additional equity or debt financing; (c) granting licenses to third parties in exchange for specified up-front and/or back end payments; and (d) developing and commercializing our products on an accelerated timeline. Management continues to exercise tight cost controls to conserve cash.

Our ability to continue as a going concern is dependent upon our accomplishment of the plans described in the preceding paragraph and eventually to attain profitable operations. The accompanying consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. If we are unable to obtain adequate capital, we could be forced to cease operations.

Developments—COVID-19 Pandemic

Due to the continued evolution of the COVID-19 pandemic since March 2020, we cannot precisely determine or quantify the impacts the pandemic will have on our business, financial conditions or results of operations. For example, although we have worked with clinical trial sites impacted by the pandemic to ensure study continuity, we have experienced and may in the future experience disruptions that could impact our clinical trials, including delays in enrolling patients in clinical trials or in sample collection, and diversion of healthcare resources from the conduct of our clinical trials.

The extent of the impact of the COVID-19 pandemic on our business remains uncertain and subject to change. If there is a subsequent outbreak of COVID-19 in the future, we may experience significant delays in our clinical development timelines, which would adversely affect our business, financial condition, and results of operations.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private placements and public offerings of our common stock. As of December 31, 2022, we had cash and cash equivalents of approximately $10.9 million.

Net cash used in operating activities was $15.3 million and $20.9 million for the years ended December 31, 2022 and December 31, 2021, respectively. The decrease in cash used in operating activities during 2022 when compared to 2021 was primarily due to a $10.0 million payment received pursuant to our master license and product supply agreement with Heska, partly offset by higher payroll costs, and higher amounts paid to suppliers during the period.

Net cash used in investing activities was $1.6 million and $1.0 million for the years ended December 31, 2022 and December 31, 2021, respectively. The increase in cash used in investing activities during 2022 was primarily due to an increase in purchases of laboratory equipment as compared to 2021.

Net cash provided by financing activities after associated costs was $6.9 million and $22.9 million for the years ended December 31, 2022 and December 31, 2021, respectively. The decrease in net cash provided by financing activities for the 2022, when compared to 2021 was primarily due to $18.9 million in net cash received from the issuance of shares of common stock in a registered public offering in February 2021, and an aggregate of $4.6 million in cash received from the issuance of shares of common stock under our “at-the-market” facilities during 2021.

This compares with $6.4 million in net cash received from the issuance of approximately 3.5 million shares of common stock in a registered public offering in August 2022 (before deducting offering expenses of $0.2 million paid by the Company), a $1.1 million loan received in August 2022 from Namur Invest Capital Risk ("Namur Invest"), a $0.5 million loan received in December 2022 from Namur Invest, and an aggregate of $0.8 million in cash received from the issuance of shares of common stock under our “at-the-market” facilities during 2022 (before deducting offering expenses of $0.2 million).

For additional information on our “at the market facilities,” refer to Note 7,*Common Stock – Equity Distribution Agreements,* of the Notes to consolidated financial statements.

The following table summarizes our approximate contractual payments due by year as of December 31, 2022.

Approximate Payments (Including Interest) Due by Year

Description	Total $	2023 $	2024 - 2027 $	2028 + $
Financing lease liabilities	541,162	57,726	230,902	252,534
Operating lease liabilities and short-term lease	696,702	291,868	404,834	-
Grants repayable	462,302	49,283	149,126	263,893
Long-term debt	4,319,826	1,268,528	2,604,499	446,799
Collaborative agreements obligations	879,805	798,032	81,773	-
Total	6,899,797	2,465,437	3,471,134	963,226

We intend to use our cash reserves to predominantly fund further research and development activities. We do not have any substantial source of revenues and expect to rely on additional future financing, through the sale of equity or debt securities, or the sale of licensing or distribution rights, to provide sufficient funding to execute our strategic plan. There is no assurance that we will be successful in raising further funds.

In the event additional financing is delayed, we will prioritize the maintenance of our research and development personnel and facilities, primarily in Belgium, and the maintenance of our patent rights. In such instance, the completion of clinical validation studies and regulatory approval processes for the purpose of bringing products to the IVD market would be delayed. In the event of an ongoing lack of financing, it may be necessary to discontinue operations, which will adversely affect the value of our common stock.

We have not attained profitable operations and are dependent upon obtaining financing to pursue any extensive activities. For these reasons, our auditors included in their report on our audited financial statements for the year ended December 31, 2022, an explanatory paragraph regarding factors that raise substantial doubt that we will be able to continue as a going concern.

Results of Operations

Comparison of the Years Ended December 31, 2022 and December 31, 2021

The following table sets forth our results of operations for the years ended on December 31, 2022, and December 31, 2021, respectively (expressed in United Stated Dollars, except outstanding share numbers and percentages).

	2022 $	2021 $	Increase (Decrease) $	Percentage Increase (Decrease) $
Royalty	2,911	-	2,911	>100%
Service	92,488	-	92,488	>100%
Product	210,993	90,035	120,958	>100%
Total Revenues	306,392	90,035	216,357	>100%
Research and development	14,572,532	13,022,411	1,550,121	12%
General and administrative	10,937,686	11,676,446	(738,760)	(6%)
Sales and marketing	6,576,246	3,724,257	2,851,989	77%
Total Operating Expenses	32,086,464	28,423,114	3,663,350	13%
Grant income	1,229,425	1,522,533	293,108	(19%)
Loss on disposal of fixed assets	-	(26,166)	26,166	<(100%)
Interest income	125,265	2,734	122,531	>100%
Interest expense	(173,087)	(155,803)	17,284	11%
Total Other Income (Expenses)	1,181,603	1,343,298	(161,695)	(12%)
Net Loss	(30,598,469)	(26,989,781)	3,608,688	13%

Revenues

Our operations are still transitioning from a research and development stage to a commercialization stage. Revenue for the year ended December 31, 2022 was $306,392 compared with $90,035 for the year ended December 31, 2021. The main source of revenues during the year ended December 31, 2022, was product sales of the Nu.Q® Vet Cancer Test and services revenue from our Nu.Q® Discover offering. The primary source of revenue during the year ended December 31, 2021, was direct sales of the Nu.Q® Vet Cancer Test through the Gastrointestinal Laboratory at Texas A&M University.

Operating Expenses

Total operating expenses increased to $32.1 million from $28.4 million for the years ended December 31, 2022 and December 31, 2021, respectively, as a result of the factors described below.

Research and Development Expenses

Research and development expenses increased to $14.6 million from $13.0 million for the years ended December 31, 2022 and December 31, 2021, respectively. The increase in overall research and development expenditures during 2022 was primarily related to higher personnel expenses offset by a reduction in stock-based compensation expenses. FTE personnel numbers within this division increased by six to sixty-three during 2022 compared to the prior year period.

	2022 $	2021 $	Change $
Personnel expenses	7,125,017	5,335,333	1,789,684
Stock based compensation	652,653	1,361,989	(709,336)
Direct research and development expenses	5,662,957	5,055,411	607,546
Other research and development	292,292	730,491	(438,199)
Depreciation and amortization	839,613	539,187	300,426
Total research and development expenses	14,572,532	13,022,411	1,550,121

General and Administrative Expenses

General and administrative expenses decreased to $10.9 million from $11.7 million for the years ended December 31, 2022 and December 31, 2021, respectively. The decrease in overall general and administrative expenditures during 2022 was primarily due to lower stock-based compensation in relation to modification of options, offset by higher personnel expenses. The FTE personnel number within this division increased by nine to twenty-two in 2022 compared to the prior year period.

	2022 $	2021 $	Change $
Personnel expenses	5,047,242	3,944,454	1,102,788
Stock-based compensation	1,393,784	2,984,253	(1,590,469)
Legal and professional fees	2,715,255	2,696,164	19,091
Other general and administrative	1,486,722	1,477,186	9,536
Depreciation and amortization	294,683	574,389	(279,706)
Total general and administrative expenses	10,937,686	11,676,446	(738,760)

Sales and Marketing Expenses

Sales and marketing expenses increased to $6.6 million from $3.7 million for the years ended December 31, 2022 and December 31, 2021, respectively. The increase in overall sales and marketing expenditures was primarily due to increased personnel expenses, stock-based compensation and direct marketing expenses. The FTE personnel number within this division increased by six to nineteen in 2022 compared to the prior year period.

	2022 $	2021 $	Change $
Personnel expenses	4,400,092	2,203,745	2,196,347
Stock-based compensation	1,068,222	774,404	293,818
Other Sales & Marketing expenses	1,053,807	746,108	307,699
Depreciation and amortization	54,125	-	54,125
Total sales and marketing expenses	6,576,246	3,724,257	2,851,989

Other Income (Expenses)

For the year ended December 31, 2022, other income decreased to approximately $1.2 million compared to other income of approximately $1.3 million for the year ended December 31, 2021. This decrease in other income was primarily due to reduced grant income received of approximately $1.2 million during 2022 compared to $1.5 million in 2021.

Net Loss

For the year ended December 31, 2022, the Company's net loss was $30.6 million, an increase of approximately $3.6 million, in comparison to a net loss of $27.0 million for the year ended December 31, 2021. The change was a result of the factors described above.

Going Concern

We have not attained profitable operations and are dependent upon obtaining external financing to continue to pursue our operational and strategic plans. For these reasons, management has determined that there is substantial doubt that the business will be able to continue as a going concern without further financing.

Off-Balance Sheet Arrangements

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

Future Equity or Debt Financings

We may seek to obtain additional capital through the sale of debt or equity securities if we deem it desirable or necessary. These sales may include the sale of equity securities from time to time through our "at the market facility" with Jefferies LLC under an equity distribution agreement dated May 20, 2022 (see Note 7, *Common Stock – Equity Distribution Agreements,* of the Notes to consolidated financial statements). However, we may be unable to obtain such additional capital when needed, or on terms favorable to us or our stockholders, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our stockholders will be reduced, stockholders may experience additional dilution, or such equity securities may provide for rights, preferences or privileges senior to those of the holders of our common stock. If additional funds are raised through the issuance of debt securities, the terms of such securities may place restrictions on our ability to operate our business.

Critical Accounting Policies and Estimates

Our consolidated financial statements and accompanying notes have been prepared in accordance with U.S. generally accepted accounting principles, ("U.S. GAAP"), applied on a consistent basis. The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods.

We also regularly evaluate estimates and assumptions related to deferred income tax asset valuation allowances, useful lives of property and equipment and intangible assets, borrowing rate used in operating lease right-of-use asset and liability valuations, impairment analysis of intangible assets and valuations of stock-based compensation.

We base our estimates and assumptions on current facts, historical experiences, information from third party professionals and various other factors 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 accrual of costs and expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from our estimates. To the extent there are material differences between the estimates and the actual results, future results of operations could be affected.

We regularly evaluate the accounting policies that we use to prepare our consolidated financial statements. A complete summary of these policies is included in the Notes to our consolidated financial statements.

We have determined that for the periods reported in this Report the following accounting policies are critical in understanding our financial condition and results of operations:

Stock-Based Compensation

The Company records stock-based compensation in accordance with ASC 718, *"Compensation – Stock Compensation".* Under the provisions of ASC 718, stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized over the employee's requisite service period, which is generally the vesting period. The fair value of our stock options and warrants is estimated using a Black-Scholes option valuation model. Restricted stock units are valued based on the closing stock price on the date of grant, refer to Note 8 of the consolidated financial statements for further details.

Impairment of Long-Lived Assets

In accordance with ASC 360, *"Property Plant and Equipment"*, the Company tests long-lived assets or asset groups for recoverability when events or changes in circumstances indicate that their carrying amount may not be recoverable. Circumstances which could trigger a review include, but are not limited to: significant decreases in the market price of the asset; significant adverse changes in the business climate or legal factors; accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of the asset; current period cash flow or operating losses combined with a history of losses or a forecast of continuing losses associated with the use of the asset; and current expectation that the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life. Recoverability is assessed based on the carrying amount of the asset and its fair value which is generally determined based on the sum of the undiscounted cash flows expected to result from the use and the eventual disposal of the asset, as well as specific appraisal in certain instances. An impairment loss is recognized when the carrying amount is not recoverable and exceeds fair value. Impairment losses of $nil and $nil were recognized during the years ended December 31, 2022 and December 31, 2021, respectively.

Foreign Currency Translation

The Company has functional currencies in Euros, U.S. Dollars and British Pounds Sterling and its reporting currency is the U.S. Dollar. Management has adopted ASC 830-20, "*Foreign Currency Matters – Foreign Currency Transactions*" All assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the balance sheet date. For revenues and expenses, the weighted average exchange rate for the period is used. Gains and losses arising on translation of foreign currency denominated transactions are included in Other Comprehensive Income.

Recently Issued Accounting Pronouncements

The Company has implemented all applicable new accounting pronouncements that are in effect. The Company does not believe that there are any other applicable new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company and are not required to disclose this information.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

VOLITIONRX LIMITED

Consolidated Financial Statements

For the Years Ended December 31, 2022 and 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of VolitionRx Limited:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of VolitionRx Limited ("the Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2022 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

License and Supply Agreement with Heska

As discussed in Note 3 to the consolidated financial statements, in March 2022, the Company entered into a license and supply agreement with Heska Corporation ("Heska"). Under the terms of the agreement, the Company granted Heska worldwide exclusive rights to the Nu.Q Vet Cancer Screening Test at the point of care, initially for the screening of lymphoma and hemangiosarcoma in dogs and non-exclusive rights to sell its Nu.Q Vet Cancer Screening Test in kit format through Heska's network of central reference laboratories. In addition, the agreement requires the Company to supply required components for point of care testing and for kits used in central laboratories. The Company received an upfront payment of $10 million during 2022 and is eligible to receive additional milestone payments upon certain commercial targets being met. In addition, the Company is eligible to receive per unit consideration for kits and components supplied under this agreement.

We have identified the performance obligations, including understanding the nature and significance of the contractual obligations, under the Heska license and supply agreement as a critical audit matter. Determining the distinct performance obligation included in the agreement required management to make judgements with respect to the appropriate application of relevant authoritative accounting guidance. Auditing these management judgements and the resulting impacts on the accounting and deferred revenue recognition for the Heska license and supply agreement required increased auditor effort.

The primary procedures we performed to address this critical audit matter included:

- Reading the license and supply agreement with Heska to gain an understanding of the contractual terms and conditions and the commitments being made in the agreement.
- Assessing the key terms in the supply and license agreement under the relevant authoritative accounting guidance to evaluate management's conclusion that contractual promises made in the license and supply agreement should constitute a single performance obligation.
- Professionals with specialized skill and knowledge were utilized by the Firm to assist in the evaluation of management's conclusions with respect to the performance obligation identified.

/s/ Sadler, Gibb & Associates, LLC

We have served as the Company's auditor since 2011.

Draper, UT
March 15, 2023

VOLITIONRX LIMITED
Consolidated Balance Sheets
(Expressed in United States Dollars, except share numbers)

	December 31, 2022 $	December 31, 2021 $
ASSETS		
Current Assets		
Cash and cash equivalents	10,867,050	20,581,313
Accounts Receivable	72,609	12,510
Prepaid expenses	784,920	598,367
Other current assets	447,566	786,642
Total Current Assets	12,172,145	21,978,832
Property and equipment, net	5,393,012	4,911,077
Operating lease right-of-use assets	619,392	383,551
Intangible assets, net	110,505	216,876
Total Assets	18,295,054	27,490,336
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities		
Accounts payable	3,043,008	1,542,457
Accrued liabilities	2,872,247	3,828,501
Deferred revenue	10,000,000	12,512
Management and directors' fees payable	71,119	71,303
Current portion of long-term debt	1,066,700	797,855
Current portion of financing lease liabilities	46,014	48,958
Current portion of operating lease liabilities	245,163	171,166
Current portion of grant repayable	41,836	43,100
Total Current Liabilities	17,386,087	6,515,852
Long-term debt, net of current portion	2,779,240	2,270,767
Finance lease liabilities, net of current portion	436,132	511,086
Operating lease liabilities, net of current portion	400,091	217,305
Grant repayable, net of current portion	420,466	253,221
Total Liabilities	21,422,016	9,768,231
STOCKHOLDERS' EQUITY (DEFICIT)		
Common Stock		
Authorized: 100,000,000 shares of common stock, at $0.001 par value; Issued and outstanding: 57,873,379 shares and 53,772,261 shares, respectively	57,873	53,772
Additional paid-in capital	164,397,468	154,730,938
Accumulated other comprehensive income	227,097	148,326
Accumulated deficit	(167,257,429)	(136,988,636)
Total VolitionRx Limited Stockholders' Equity (Deficit)	(2,574,991)	17,944,400
Non-controlling interest	(551,971)	(222,295)
Total Stockholders' Equity (Deficit)	(3,126,962)	17,722,105
Total Liabilities and Stockholders' Equity (Deficit)	18,295,054	27,490,336

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

VOLITIONRX LIMITED
Consolidated Statements of Operations and Comprehensive Loss
(Expressed in United States Dollars, except share numbers)

	For the year ended	
	December 31, 2022 $	December 31, 2021 $
Revenues		
Royalty	2,911	-
Service	92,488	-
Product	210,993	90,035
Total Revenues	306,392	90,035
Operating Expenses		
Research and development	14,572,532	13,022,411
General and administrative	10,937,686	11,676,446
Sales and marketing	6,576,246	3,724,257
Total Operating Expenses	32,086,464	28,423,114
Operating Loss	(31,780,072)	(28,333,079)
Other Income (Expenses)		
Grant income	1,229,425	1,522,533
Loss on disposal of fixed assets	-	(26,166)
Interest income	125,265	2,734
Interest expense	(173,087)	(155,803)
Total Other Income	1,181,603	1,343,298
Net Loss	(30,598,469)	(26,989,781)
Net Loss attributable to Non-Controlling Interest	329,676	175,116
Net Loss attributable to VolitionRx Limited Stockholders	(30,268,793)	(26,814,665)
Other Comprehensive Income (Loss)		
Foreign currency translation adjustments	78,771	208,304
Net Comprehensive Loss	(30,519,698)	(26,781,477)
Net Loss Per Share – Basic and Diluted attributable to VolitionRx Limited Stockholders	(0.55)	(0.51)
Weighted Average Shares Outstanding – Basic and Diluted	55,350,401	52,655,885

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

VOLITIONRX LIMITED
Consolidated Statement of Stockholders' Equity (Deficit)
For the Years Ended December 31, 2022 and 2021
(Expressed in United States Dollars, except share numbers)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Non Controlling	
	Shares	Amount	Capital	Income (Loss)	Deficit	Interest	Total
	#	$	$	$	$	$	$
Balance, December 31, 2020	48,607,017	48,607	126,526,239	(59,978)	(110,173,971)	(47,179)	16,293,718
Common stock issued for cashless exercise of stock options	77,451	77	(77)	-	-	-	-
Common stock issued for settlement of RSUs	24,712	25	(25)	-	-	-	-
Common stock issued in public offerings, net	5,063,081	5,063	23,214,581	-	-	-	23,219,644
Tax withholdings paid related to stock-based compensation	-	-	(130,426)	-	-	-	(130,426)
Stock-based compensation	-	-	2,670,297	-	-	-	2,670,297
Stock-based compensation in relation to modification of options	-	-	2,450,349	-	-	-	2,450,349
Foreign currency translation	-	-	-	208,304	-	-	208,304
Net loss for the Year	-	-	-	-	(26,814,665)	(175,116)	(26,989,781)
Balance, December 31, 2021	53,772,261	53,772	154,730,938	148,326	(136,988,636)	(222,295)	17,722,105
Common stock issued for settlement of RSUs	297,289	297	(297)	-	-	-	-
Common stock issued in public offerings, net	3,803,829	3,804	6,732,640	-	-	-	6,736,444
Tax withholdings paid related to stock-based compensation	-	-	(180,472)	-	-	-	(180,472)
Stock-based compensation	-	-	3,114,659	-	-	-	3,114,659
Foreign currency translation	-	-	-	78,771	-	-	78,771
Net loss for the Year	-	-	-	-	(30,268,793)	(329,676)	(30,598,469)
Balance, December 31, 2022	57,873,379	57,873	164,397,468	227,097	(167,257,429)	(551,971)	(3,126,962)

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

VOLITIONRX LIMITED
Consolidated Statements of Cash Flows
(Expressed in United States Dollars)

	For the year ended	
	December 31, 2022 $	**December 31, 2021 $**
Operating Activities:		
Net loss	(30,598,469)	(26,989,781)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	936,084	945,367
Amortization of operating lease right-of-use assets	253,864	199,793
Loss on disposal of fixed assets	-	26,166
Stock based compensation	3,114,659	2,670,297
Stock-based compensation in relation to modification of options	-	2,450,349
Changes in operating assets and liabilities:		
Prepaid expenses	433,995	(295,189)
Accounts receivable	(72,609)	(12,510)
Other current assets	351,514	(202,801)
Deferred revenue	9,987,488	12,512
Accounts payable and accrued liabilities	548,611	522,220
Management and directors' fees payable	(184)	16,129
Operating lease liabilities	(232,695)	(196,471)
Net Cash Used In Operating Activities	(15,277,742)	(20,853,919)
Investing Activities:		
Purchases of property and equipment	(1,570,182)	(973,559)
Net Cash Used In Investing Activities	(1,570,182)	(973,559)
Financing Activities:		
Net proceeds from issuance of common shares	6,736,444	23,219,644
Tax withholdings paid related to stock-based compensation	(180,472)	(130,426)
Proceeds from grants repayable	218,445	37,631
Proceeds from long-term debt	1,523,098	592,423
Payments on long-term debt	(1,268,386)	(755,721)
Payments on grants repayable	(45,664)	(47,789)
Payments on financing leases	(45,433)	(58,210)
Net Cash Provided By Financing Activities	6,938,032	22,857,552
Effect of foreign exchange on cash and cash equivalents	195,629	106,502
Net Change in Cash and Cash Equivalents	(9,714,263)	1,136,576
Cash and Cash Equivalents – Beginning of Year	20,581,313	19,444,737
Cash and Cash Equivalents – End of Year	10,867,050	20,581,313
Supplemental Disclosures of Cash Flow Information:		
Interest paid	173,087	155,803
Income tax paid	-	-
Non-Cash Financing Activities:		
Common Stock issued on exercises of stock options and warrants and settlement of RSUs	297	102
Offering costs from issuance of common stock	427,443	218,459
Non-cash Note Payable	620,549	-

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

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 1 - Nature of Operations

The Company was incorporated under the laws of the State of Delaware on September 24, 1998. On September 22, 2011, the Company filed a Certificate for Renewal and Revival of Charter with the Secretary of State of Delaware. Pursuant to Section 312(1) of the Delaware General Corporation Law, the Company was revived under the new name of "VolitionRX Limited" and the name change became effective on October 11, 2011. On October 7, 2016, the Company amended its Certificate of Incorporation to reflect a name change to "VolitionRx Limited."

On October 6, 2011, the Company entered into a share exchange agreement with Singapore Volition Pte. Limited, a Singapore corporation incorporated on August 5, 2010 ("Singapore Volition"), and the shareholders of Singapore Volition. Pursuant to the terms of the share exchange agreement, the former shareholders of Singapore Volition held 85% of the issued and outstanding common shares of the Company. The issuance was deemed to be a reverse acquisition for accounting purposes and as such, Singapore Volition is regarded as the predecessor of the Company. The number of shares outstanding and per share amounts of the Company have been restated to recognize the foregoing recapitalization.

The Company's principal business objective through its subsidiaries is to develop and bring to market simple, easy to use, cost effective blood tests designed to help diagnose and monitor a range of life-altering diseases, including some cancers and diseases associated with NETosis such as sepsis and COVID-19. The tests are based on the science of Nucleosomics™, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid – an indication that disease is present. The Company has two wholly owned subsidiaries, Volition Global Services SRL ("Volition Global") which was formed in August 2021 and Singapore Volition. Singapore Volition has one wholly owned subsidiary, Belgian Volition SRL, a Belgium private limited liability company ("Belgian Volition"), which it acquired in September 2010. Belgian Volition has four subsidiaries, Volition Diagnostics UK Limited ("Volition Diagnostics"), which was formed in November 2015, Volition America, Inc. ("Volition America"), which was formed in February 2017, Volition Germany GmbH ("Volition Germany"), which was acquired in January 2020, as well as its majority-owned subsidiary Volition Veterinary Diagnostics Development LLC ("Volition Vet"), which was formed in June 2019. Following the acquisition of Singapore Volition in 2011, the Company's fiscal year end was changed from August 31 to December 31.

Note 2 – Liquidity and Going Concern Assessment

The Company's consolidated financial statements are prepared using accounting principles generally accepted in the United States of America ("U.S. GAAP"), applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has incurred losses since inception of $167.3 million, has negative cash flows from operations, and has minimal revenues, which creates substantial doubt about its ability to continue as a going concern for a period at least one year from the date of issuance of these consolidated financial statements.

The future of the Company as an operating business will depend on its ability to obtain sufficient capital contributions, financing and/or generate revenues as may be required to sustain its operations. Management plans to address the above as needed by, (a) securing additional grant funds, (b) obtaining additional financing through debt or equity transactions; (c) granting licenses and/or distribution rights to third parties in exchange for specified up-front and/or back-end payments, and (d) developing and commercializing its products on an accelerated timeline. Management continues to exercise tight cost controls to conserve cash.

The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish the plans described in the preceding paragraph and to eventually attain profitable operations. The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. If the Company is unable to obtain adequate capital, it could be forced to cease operations.

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements of the Company have been prepared in accordance with U.S. GAAP and are expressed in US dollars. The Company's fiscal year end is December 31.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company also regularly evaluates estimates and assumptions related to deferred income tax asset valuation allowances, useful lives of property and equipment and intangible assets, borrowing rate used in operating lease right-of-use asset and liability valuations, impairment analysis of intangible assets and valuations of stock-based compensation.

The Company bases its estimates and assumptions on current facts, historical experiences and various other factors 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 accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations could be affected.

Principles of Consolidation

The accompanying consolidated financial statements for the year ended December 31, 2022 include the accounts of the Company and its subsidiaries. The Company has two wholly owned subsidiaries, Singapore Volition Pte. Limited and Volition Global Services SRL. Singapore Volition has one wholly owned subsidiary, Belgian Volition SRL. Belgian Volition has four subsidiaries, Volition Diagnostics UK Limited, Volition America, Inc, Volition Germany GmbH, and its one majority owned subsidiary Volition Veterinary Diagnostics Development LLC. See Note 10 (f), *Commitments and Contingencies – Other Commitments*, for more information regarding Volition Vet, Volition Germany and Volition America. All intercompany balances and transactions have been eliminated in consolidation.

Reclassification

Certain amounts presented in previously issued financial statements have been reclassified to be consistent with the current period presentation. In the statement of operations and comprehensive loss, the Company has reclassified the prior year comparative amounts of research and development, sales and marketing and general and administrative expenses to be consistent with the current year classification.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with a maturity of three months or less at the time of issuance to be cash equivalents. As of December 31, 2022, and December 31, 2021, the Company had $10,867,050 and $20,581,313, respectively, in cash and cash equivalents. As of December 31, 2022, and December 31, 2021, the Company had $10,079,089 and $19,753,878, respectively, in its domestic accounts in excess of Federal Deposit insured limits. As of December 31, 2022, and December 31, 2021, the Company had $1,725,981 and $134,134, respectively, in its foreign accounts in excess of the Belgian Deposit insured limits. As of December 31, 2022, and December 31, 2021, the Company had $100,601 and $102,514, respectively, in its foreign accounts in excess of the Singapore Deposit insured limits. As of December 31, 2022, and December 31, 2021, the Company had $326,631 and $142,410, respectively, in its foreign accounts in excess of the UK Deposit insured limits.

Accounts Receivable

Trade accounts receivable are stated at the amount the Company expects to collect. Due to the nature of the accounts receivable balance, the Company believes the risk of doubtful accounts is minimal and therefore no allowance is recorded. If the financial condition of the Company's customers were to deteriorate, adversely affecting their ability to make payments, additional allowances would be required. The Company may provide for estimated uncollectible amounts through a charge to earnings and a credit to a valuation allowance. Balances that remain outstanding after the Company has used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable. As of December 31, 2022, the accounts receivable balance was $72,609 and the allowance for doubtful accounts was $nil.

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies (continued)

Property and Equipment

Property and equipment are stated at historical cost and depreciated over the useful life of the asset using the straight-line method. Useful lives are assigned to assets depending on their category. For details regarding property and equipment, refer to Note 4.

Basic and Diluted Net Loss Per Share

The Company computes net loss per share in accordance with Accounting Standards Codification ("ASC") 260, *"Earnings Per Share,"* which requires presentation of both basic and diluted earnings per share ("EPS") on the face of the income statement. Basic EPS is computed by dividing net loss available to common stockholders (numerator) by the weighted average number of shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. As of December 31, 2022, and December 31, 2021, 7,787,013 and 6,323,268, respectively, of potential common shares equivalents from stock options, RSUs and warrants were excluded from the diluted EPS calculations as their effect is anti-dilutive.

Foreign Currency Translation

The Company has functional currencies in Euros, US Dollars and British Pounds Sterling and its reporting currency is the US Dollar. Management has adopted ASC 830-20, *"Foreign Currency Matters – Foreign Currency Transactions"*. All assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the balance sheet date. For revenues and expenses, the weighted average exchange rate for the period is used. Gains and losses arising on translation of foreign currency denominated transactions are included in other comprehensive income (loss).

Fair Value Measurements

Pursuant to ASC 820, *"Fair Value Measurements and Disclosures,"* an entity is required to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 establishes a fair value hierarchy based on the level of independent, objective evidence surrounding the inputs used to measure fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. ASC 820 prioritizes the inputs into three levels that may be used to measure fair value:

Level 1
Level 1 applies to assets or liabilities for which there are quoted prices in active markets for identical assets or liabilities.

Level 2
Level 2 applies to assets or liabilities for which there are inputs other than quoted prices that are observable for the assets or liabilities such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical assets or liabilities in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data.

Level 3
Level 3 applies to assets or liabilities for which there are unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of the assets or liabilities.

The Company's financial instruments consist principally of cash, accounts payable, accrued liabilities, notes payable, and amounts due to related parties. Pursuant to ASC 820, the fair value of cash is determined based on "Level 1" inputs, which consists of quoted prices in active markets for identical assets. The Company believes that the recorded values of all of our other financial instruments approximate their current fair values because of their nature and respective maturity dates or durations.

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies (continued)

Other Comprehensive Income (Loss)

ASC 220, "*Other Comprehensive Income/(Loss)",* establishes standards for the reporting and display of other comprehensive loss and its components in the financial statements. As of December 31, 2022, the Company had $227,097 of accumulated other comprehensive income, relating to foreign currency translation.

Income Taxes

Potential benefits of income tax losses are not recognized in the accounts until realization is more likely than not. The Company has adopted ASC 740,*"Accounting for Income Taxes"* as of its inception. Pursuant to ASC 740, the Company is required to compute tax asset benefits for net operating losses carried forward. The potential benefits of net operating losses have not been recognized in these consolidated financial statements because the Company cannot be assured it is more likely than not it will utilize the net operating losses carried forward in future years. Refer to Note 9 for further details.

Revenue Recognition

The Company adopted ASC 606, "*Revenue from Contracts with Customers,"* effective January 1, 2019. Under ASC 606, the Company recognizes revenues when the customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company recognizes revenues following the five-step model prescribed under ASC 606: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) the Company satisfies the performance obligation(s).

The Company generates product revenues from the sale of its Nu.Q® Vet Cancer Test, from the sale of nucleosomes, and from the sale of research use only kits. In addition, revenue is received from external third parties for services the Company performs for them in its laboratory.

Revenues, and their respective treatment for financial reporting purposes under ASC 606, are as follows:

Royalty

The Company receives royalty revenues on the net sales recognized during the period in which the revenue is earned, and the amount is determinable from the licensee. These are presented under "Royalty" under the consolidated statements of operations. The Company does not have future performance obligations under this revenue stream. In accordance with ASC 606, the Company records these revenues based on estimates of the net sales that occurred during the relevant period from the licensee. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known.

Product

The Company includes revenue from product sales recognized during the period in which goods are shipped to third parties, and the amount is deemed collectable from the third parties. These are presented in "Product" in the consolidated statements of operations and comprehensive loss.

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies (continued)

Revenue Recognition (continued)

Service

The Company includes revenue recognized from laboratory services performed in the Company's laboratory on behalf of third parties under "Service" under the consolidated statements of operations.

For each development and/or commercialization agreement that results in revenues, the Company identifies all performance obligations, aside from those that are immaterial, which may include a license to intellectual property and know-how, development activities and/or transition activities. In order to determine the transaction price, in addition to any upfront payment, the Company estimates the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. The Company constrains the estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur throughout the life of the contract. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company's control that could result in a significant reversal of revenue. In making these assessments, the Company considers the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Licensing

The Company includes revenue recognized from the licensing of certain rights to third parties in "Licensing" in the consolidated statements of operations and comprehensive loss. For each development and/or commercialization agreement that results in revenues, the Company identifies all performance obligations, aside from those that are immaterial, which may include a license to intellectual property and know-how, development activities and/or transition activities. In order to determine the transaction price, in addition to any upfront payment, the Company estimates the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. The Company constrains (reduces) the estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur throughout the life of the contract. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company's control that could result in a significant reversal of revenue. In making these assessments, the Company considers the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Revenue from Heska License Agreement

On March 28, 2022, Belgian Volition entered into a Master License and Supply Agreement (the "License Agreement") with Heska Corporation ("Heska"), pursuant to which Belgian Volition granted Heska worldwide exclusive rights to sell the Nu.Q® Vet Cancer Test at the point of care ("POC") initially for the screening of lymphoma and hemangiosarcoma in dogs ("Canine Lymphoma & HSA"), and non-exclusive rights to sell its Nu.Q® Vet Cancer Test in kit format ("Kits") through Heska's network of central reference laboratories ("Central Lab") initially for Canine Lymphoma & HSA.

Under and subject to the terms of the License Agreement, Belgian Volition received an upfront payment of $10.0 million in 2022, and is eligible to receive further milestone payments of (i) $6.5 million upon the first commercial sale by or on behalf of Heska of a POC screening test for Canine Lymphoma & HSA, (ii) $6.5 million upon the first commercial sale by or on behalf of Heska of a POC monitoring test for the same conditions, and (iii) $5.0 million upon the first commercial sale by or on behalf of Heska of a screening or monitoring test for lymphoma in felines. The License Agreement contains additional time-based triggers for the payment of the above-described milestones as well. Any further expansion of the License Agreement to cover other cancer and non-cancer indications is subject to negotiation between the parties.

Belgian Volition will also supply Central Lab Kits and will receive a pre-agreed price per test, adjusted annually for inflation. The price per test for POC key components ("Key Components") is also discounted to reflect the lower cost to Belgian Volition and additional assembly costs for Heska, as well as consideration for Heska's upfront and milestone payments. Heska will assemble the Key Components for use at the POC, and is additionally responsible for marketing and distribution efforts and related costs.

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies (continued)

Revenue Recognition (continued)

The License Agreement may be terminated by either party for a material breach by the other party, subject to notice and cure provisions, or in the event of the other party's insolvency. Heska also has the option to terminate if it is unable to adapt the Key Components for use on a POC platform. Unless earlier terminated, the License Agreement will continue in effect for an initial term of 22 years for POC and 5 years for Central Lab, with the Central Lab term then continuing on a rolling one-year basis for the POC term.

According to ASC Topic 606, "*Revenue from Contracts with Customers*", a performance obligation is a commitment to provide a distinct good or service or a series of distinct goods or services. Goods and services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. A good or service promised to a customer is distinct if the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

In conjunction with the License Agreement, the Company evaluated whether or not the performance obligations granted under the License Agreement were distinct and concluded that they were not distinct as Heska could not benefit from the license without the supply (manufacturing) services. The supply services are highly specialized and are dependent on the supply of the product from the Company. As such, the performance obligations granted under the License Agreement were combined to constitute a single performance obligation and the Company accounts for them as a single contract.

During the first quarter of 2022, the Company received a $10.0 million upfront payment under the License Agreement, which is included as deferred revenue on the accompanying consolidated balance sheet as of December 31, 2022. The Company allocated the upfront payment and any milestone payments that were not constrained to the single performance obligation in the contract. The Company expects to recognize the $10.0 million upfront payment and any milestone amounts not constrained under the License Agreement over time using an output method based on Key Components and Kits supplied to Heska. As of December 31, 2022, the remaining $18.0 million in milestone payments under the License Agreement remains constrained and will not begin to be recognized until such amount becomes unconstrained.

In determining the transaction price, the Company analyzed the variable consideration and whether or not such variable consideration was constrained. The Company will reassess this variable consideration at each reporting period and adjust the transaction price, if necessary. The total Key Components and Kits that the Company expects to manufacture for Heska over the life of the contract will be a significant judgment in recognizing revenue once the Company begins to supply product to Heska.

Deferred Revenue (Contract Liabilities) and Contract Assets

Deferred revenue consists of amounts for which the Company has an unconditional right to bill, and/or amounts for which payment has been received (including non-refundable amounts) but have not been recognized as revenue because the related performance obligations are deemed incomplete. As of December 31, 2022, the Company recorded $10.0 million as deferred revenue in respect of a non-refundable payment received in relation to a licensing and product supply agreement with Heska Corporation. As of December 31, 2021, the Company recorded $12,512 as deferred revenue.

Contract assets include costs and services incurred on contracts with open performance obligations. These contract assets were immaterial as of December 31, 2022.

Research and Development

In accordance with ASC 730, the Company follows the policy of expensing its research and development costs in the period in which they are incurred. The Company incurred research and development expenses of $14.6 million and $13.0 million during the years ended December 31, 2022 and 2021, respectively.

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 3 - Summary of Significant Accounting Policies (continued)

Impairment of Long-Lived Assets

In accordance with ASC 360, *"Property Plant and Equipment",* the Company tests long-lived assets or asset groups for recoverability when events or changes in circumstances indicate that their carrying amount may not be recoverable. Circumstances which could trigger a review include, but are not limited to: significant decreases in the market price of the asset; significant adverse changes in the business climate or legal factors; accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of the asset; current period cash flow or operating losses combined with a history of losses or a forecast of continuing losses associated with the use of the asset; and current expectation that the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life. Recoverability is assessed based on the carrying amount of the asset and its fair value which is generally determined based on the sum of the undiscounted cash flows expected to result from the use and the eventual disposal of the asset, as well as specific appraisal in certain instances. An impairment loss is recognized when the carrying amount is not recoverable and exceeds fair value. Impairment losses of $nil and $nil were recognized during the years ended December 31, 2022 and December 31, 2021, respectively.

Stock-Based Compensation

The Company records stock-based compensation in accordance with ASC 718, "*Compensation – Stock Compensation"*. Under the provisions of ASC 718, stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized over the employee's requisite service period, which is generally the vesting period. The fair value of our stock options and warrants is estimated using a Black-Scholes option valuation model. Restricted stock units are valued based on the closing stock price on the date of grant. The estimated fair value of RSUs that include a market vesting condition will be measured on the grant date using a Monte Carlo Simulation model. Refer to Note 8 for further details.

Leases

The Company accounts for leases in accordance with ASC Topic 842, "Leases." The Company determines whether a contract is a lease at contract inception or for a modified contract at the modification date. At inception or modification, the Company recognizes right-of-use assets ("ROU") and related lease liabilities on the balance sheet for all leases greater than one year in duration. Lease liabilities and their corresponding ROU assets are initially measured at the present value of the unpaid lease payments as of the lease commencement date. If the lease contains a renewal and/or termination option, the exercise of the option is included in the term of the lease if the Company is reasonably certain that a renewal or termination option will be exercised. As the Company's leases do not provide an implicit rate, the Company uses an estimated incremental borrowing rate ("IBR") based on the information available at the commencement date of the respective lease to determine the present value of future payments. The IBR is determined by estimating what it would cost the Company to borrow a collateralized amount equal to the total lease payments over the lease term based on the contractual terms of the lease and the location of the leased asset.

Operating lease payments are recognized as an expense on a straight-line basis over the lease term in equal amounts of rent expense attributed to each period during the term of the lease, regardless of when actual payments are made. This generally results in rent expense in excess of cash payments during the early years of a lease and rent expense less than cash payments in later years. The difference between rent expense recognized and actual rental payments is typically represented as the spread between the ROU asset and lease liability.

When calculating the present value of minimum lease payments, we account for leases as one single lease component if a lease has both lease and non-lease fixed cost components. Variable lease and non-lease cost components are expensed as incurred.

We do not recognize ROU assets and lease liabilities for short-term leases that have an initial lease term of 12 months or less. We recognize the lease payments associated with short-term leases as an expense on a straight-line basis over the lease term.

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Note 3 - Summary of Significant Accounting Policies (continued)

Grant Income

The Company receives funding from public bodies for a proportion of the costs of specific projects. Funds are received in line with claims submitted for the agreed expenditure. The Company recognizes grant income once claims submitted are approved and funds are received. General working capital funding received at the commencement of a project is treated as deferred income and is recorded in accrued liabilities until it has been utilized for the expenditure claimed. Funding received that is repayable is shown as a liability.

The Company has implemented all new accounting pronouncements that are in effect. The Company does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

COVID-19 Pandemic Impact

As of the date of this filing, there continue to be widespread concerns regarding the ongoing impacts and disruptions caused by the COVID-19 pandemic in the regions in which the Company operates. As a result of the impacts of the COVID-19 pandemic, the Company has experienced and may continue to experience disruptions to its clinical trials, including patient enrollment and sample collection delays.

Although the Company has taken steps to mitigate the impacts of the COVID-19 pandemic, the extent to which the pandemic will impact its business, financial condition, and results of operations in future periods is highly uncertain and will be affected by a number of factors outside of the Company’s control. These include the duration and extent of the COVID-19 pandemic, the development of new variants of the COVID-19 virus that may be more contagious or virulent than previous versions, the scope of mandated or recommended containment and mitigation measures, the effect of government stabilization and recovery efforts, and the success of vaccine distribution programs.

Recent Accounting Pronouncements

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers. This ASU amends ASC 805 to require acquiring entities to apply ASC 606 to recognize and measure contract assets and contract liabilities in business combinations. The standard is effective for the Company's fiscal year beginning January 1, 2023, with early adoption permitted. The adoption of this standard is not expected to have a material effect on our financial position, results of operations, or cash flows.

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Note 4 - Property and Equipment

The Company's property and equipment consist of the following amounts as of December 31, 2022 and December 31, 2021:

	Useful Life	Cost $	Accumulated Depreciation $	December 31, 2022 Net Carrying Value $
Computer hardware and software	3 years	656,759	497,306	159,453
Laboratory equipment	5 years	4,190,289	1,951,387	2,238,902
Office furniture and equipment	5 years	358,575	239,436	119,139
Buildings	30 years	2,054,332	298,397	1,755,935
Building improvements	5-15 years	1,317,132	326,337	990,795
Land	Not amortized	128,788	-	128,788
		8,705,875	3,312,863	5,393,012

	Useful Life	Cost $	Accumulated Depreciation $	December 31, 2021 Net Carrying Value $
Computer hardware and software	3 years	599,944	474,169	125,775
Laboratory equipment	5 years	3,032,108	1,434,347	1,597,761
Office furniture and equipment	5 years	293,427	213,244	80,183
Buildings	30 years	2,177,641	243,750	1,933,891
Building improvements	5-15 years	1,293,258	256,309	1,036,949
Land	Not amortized	136,518	-	136,518
		7,532,896	2,621,819	4,911,077

During the years ended December 31, 2022 and December 31, 2021, the total capital expenditure was $1.6 million and $1.1 million, respectively, the majority of which was from purchases of laboratory equipment. For further details refer to Note 10 (a) for Finance Leases included in *Property, Plant and Equipment.*

During the years ended December 31, 2022 and December 31, 2021, the Company recognized $865,262 and $812,109, respectively, in depreciation expense.

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Note 5 - Intangible Assets

The Company's intangible assets consist of patents, mainly acquired in the acquisition of Belgian Volition. The patents are being amortized over the assets' estimated useful lives, which range from 8 to 20 years.

	Cost $	Accumulated Amortization $	December 31, 2022 Net Carrying Value $
Patents	1,104,103	993,598	110,505

	Cost $	Accumulated Amortization $	December 31, 2021 Net Carrying Value $
Patents	1,178,135	961,259	216,876

During the years ended December 31, 2022 and December 31, 2021, the Company recognized $75,558 and $91,645, respectively, in amortization expense.

The Company amortizes the long-lived assets on a straight-line basis with terms ranging from8 to 20 years. The annual estimated amortization schedule over the next five years is as follows:

Remaining Life	Remaining Amortization
2023	$ 85,636
2024	$ 24,869
Total Intangible Assets	**$ 110,505**

The Company periodically reviews its long-lived assets to ensure that their carrying value does not exceed their fair market value. The Company carried out such a review in accordance with ASC 360 as of December 31, 2022. The result of this review confirmed that the ongoing value of the patents was not impaired as of December 31, 2022.

Note 6 - Related Party Transactions

See Note 7 for common stock issued to related parties and Note 8 for stock options, warrants and RSUs issued to related parties. The Company has agreements with related parties for the purchase of products and consultancy services which are accrued under accruals and management and directors' fees payable (see consolidated balance sheets).

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Note 7 - Common Stock

As of December 31, 2022, the Company was authorized to issue100 million shares of common stock par value $0.001 per share, of which 57,873,379 and 53,772,261 shares were issued as of December 31, 2022 and December 31, 2021, respectively.

2022

Stock Option Exercises

During the year ended December 31, 2022 no shares of common stock were issued pursuant to the exercise of stock options.

2021

Stock Option Exercises

During the year ended December 31, 2021 we issued a total of77,451 shares of common stock from the cashless exercise of options, as follows:

Date	Stock Incentive Plan	Stock Options	Price Per Share	Shares Issued
		#	$	#
January 13 - March 19, 2021	2011	7,634	3.35	948
February 2, 2021	2011	20,000	3.80	6,181
February 8, 2021	2011	15,000	4.00	5,769
February 8, 2021	2015	100,000	5.00	19,446
February 8 - February 9, 2021	2015	85,000	4.00	26,357
February 8, 2021	2015	50,000	3.25	18,750
		277,634		77,451

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Note 7 - Common Stock (continued)

RSU Settlements

2022

During the year ended December 31, 2022 we issued a total of297,289 shares of common stock from the settlement of RSUs, as follows:

Date	Restricted Stock Units Vested	Price Settled Per Share	Shares Issued	Shares Withheld for Tax
	#	$	#	#
March 25, 2022	15,000	3.01	15,000	-
April 13, 2022	26,250	2.95	21,712	4,538
May 1, 2022	50,000	2.79	35,000	15,000
August 3, 2022	230,102	1.97	191,992	38,110
September 7, 2022	12,000	1.65	7,038	4,962
October 4, 2022	19,905	1.46	13,022	6,883
November 1, 2022	21,750	1.97	12,344	9,406
December 15, 2022	2,000	1.97	1,181	819
	377,007		297,289	79,718

2021

During the year ended December 31, 2021 we issued a total of24,712 shares of common stock from the settlement of RSUs, as follows:

Date	Restricted Stock Units Vested	Price Settled Per Share	Shares Issued	Shares Withheld for Tax
	#	$	#	#
January 20, 2021	5,000	4.10	3,000	2,000
April 21, 2021	26,250	3.44	21,712	4,538
	31,250		24,712	6,538

Equity Capital Raises

2022

On July 29, 2022, the Company entered into an underwriting agreement with Newbridge Securities Corporation (“Newbridge”) in connection with an underwritten public offering of 3,450,000 shares of the Company’s common stock, which includes Newbridge’s exercise in full of its overallotment option (of 450,000 shares), pursuant to the Company’s “shelf” registration statement on Form S-3 (declared effective by the SEC on November 8, 2021, File No. 333-259783) (as amended and supplemented from time to time, the “2021 Form S-3”). Newbridge purchased the shares from the Company at a weighted average price of $1.87 per share. The offering closed on August 2, 2022. The Company received net proceeds of approximately $6.4 million from the offering before deducting offering expenses of $0.2 million paid by the Company.

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Note 7 - Common Stock (continued)

***Equity Capital Raises* (continued)**

2021

On February 10, 2021, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co. ("Cantor") in connection with an underwritten public offering of 3,809,524 shares of the Company's common stock, pursuant to the Company's "shelf" registration statement on Form S-3 (declared effective by the SEC on September 28, 2018, File No. 333-227248) (the "2018 Form S-3"). Cantor purchased the shares from the Company at a price of $4.9533 per share, and elected not to exercise an option to purchase up to an additional 571,428 shares of common stock at the same price per share. The offering closed on February 12, 2021. The Company received net proceeds of approximately $18.9 million from the offering before deducting offering expenses.

Equity Distribution Agreements

2022

On May 20, 2022, the Company entered into an equity distribution agreement (the "2022 EDA") with Jefferies LLC ("Jefferies") to sell shares of the Company's common stock, with an aggregate offering price of up to $25.0 million, from time to time through an "at the market" offering pursuant to the Company's 2021 Form S-3 through Jefferies acting as the Company's agent and/or principal. The Company is not obligated to sell any shares under the 2022 EDA. As of December 31, 2022, the Company raised aggregate net proceeds (net of broker commissions and fees) of approximately $0.8 million under the 2022 EDA through the sale of 350,829 shares of common stock, before deducting offering expenses. See Note 11 for additional details regarding the Company's equity distribution agreements subsequent to December 31, 2022.

From January 1, 2022 through May 7, 2022, the Company raised aggregate net proceeds (net of broker commissions and fees) of approximately $9,500 under the 2021 EDA (as defined below) through the sale of 3,000 shares of its common stock. The Company terminated the 2021 EDA effective May 7, 2022.

2021

On September 24, 2021, the Company entered into an equity distribution agreement (the "2021 EDA") with Cantor and Oppenheimer & Co. Inc. ("Oppenheimer") to sell shares of the Company's common stock, with an aggregate offering price of up to $25.0 million, from time to time through an "at the market" offering pursuant to the Company's 2021 Form S-3 through Cantor and Oppenheimer acting as the Company's agents and/or principals. From the 2021 EDA's effectiveness on November 8, 2021 through December 31, 2021, the Company raised aggregate net proceeds (net of broker commissions and fees) of approximately $0.7 million through the sale of 190,600 shares of its common stock.

On November 10, 2020, the Company entered into an equity distribution agreement (the "2020 EDA") with Cantor and Oppenheimer to sell shares of the Company's common stock, with an aggregate offering price of up to $25.0 million, from time to time through an "at the market" offering pursuant to the 2018 Form S-3 through Cantor and Oppenheimer acting as the Company's agents and/or principals. During the year ended December 31, 2021 (and from inception of the 2020 EDA), the Company raised aggregate net proceeds (net of broker commissions and fees) of $2.7 million under the 2020 EDA through the sale of 754,348 shares of its common stock. The Company terminated the 2020 EDA effective November 8, 2021.

On September 7, 2018, the Company entered into an equity distribution agreement (as amended, the "2018 EDA") with Oppenheimer to sell shares of the Company's common stock, with an aggregate offering price of up to $10.0 million, from time to time through an "at the market" offering pursuant to the 2018 Form S-3 through Oppenheimer acting as the Company's agent and/or principal. The Company utilized the 2018 EDA in full during the three months ended March 31, 2021, and raised aggregate net proceeds (net of broker commissions and fees) of approximately $9.7 million under the 2018 EDA since inception through the sale of 2,539,606 shares of its common stock.

During the year ended December 31, 2021, the Company raised aggregate net proceeds (net of broker commissions and fees) of $1.2 million under the 2018 EDA through the sale of 308,609 shares of its common stock.

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Note 7 - Common Stock (continued)

2022 and 2021

Issuances Upon Warrant Exercises

For the years ended December 31, 2022 and December 31, 2021 no warrants were exercised.

Note 8 - Stock-Based Compensation

a) Warrants

The following table summarizes the changes in warrants outstanding of the Company during the year ended December 31, 2022 and December 31, 2021:

	Number of Warrants	Weighted Average Exercise Price $
Outstanding at December 31, 2020	175,000	2.75
Granted	310,000	4.52
Exercised	-	-
Expired	-	-
Outstanding at December 31, 2021	485,000	3.88
Granted	54,000	3.05
Exercised	-	-
Expired	-	-
Outstanding at December 31, 2022	539,000	3.80
Exercisable at December 31, 2022	485,000	3.88

2022

Effective April 4, 2022, the Company granted a warrant to purchase 54,000 shares of common stock to a Company employee for services to the Company and/or its subsidiaries. This warrant shall vest in two equal installments at 12 months and 24 months from the grant date, subject to continued service and expire on April 4, 2028 and April 4, 2029, respectively, with an exercise price of $3.05 per share. The Company has calculated the estimated fair market value of this warrant at $80,901, using the Black-Scholes model and the following assumptions: term 3.5 years, stock price $2.95, exercise price $3.05, 71.07% volatility, 2.53% risk-free rate, and no forfeiture rate.

2021

Effective January 1, 2021, the Company granted warrants to purchase 125,000 shares of common stock to a Company employee for services to the Company. These warrants vest on January 1, 2022 (subject to continued employment through such date) and expire on January 1, 2027, with an exercise price of $3.95 per share. The Company has calculated the estimated fair market value of these warrants at $242,877, using the Black-Scholes model and the following assumptions: term 3.5 years, stock price $3.80, exercise price $3.95, 74.53% volatility, 0.50% risk free rate, and no forfeiture rate.

Effective February 1, 2021, the Company granted warrants to purchase 185,000 shares of common stock to a Company employee for services to the Company. These warrants vested on February 1, 2022 (subject to continued employment through such date) and expire on February 1, 2027, with an exercise price of $4.90 per share. The Company has calculated the estimated fair market value of these warrants at $459,352, using the Black-Scholes model and the following assumptions: term 3.5 years, stock price $4.80, exercise price $4.90, 75.03% volatility, 0.59% risk free rate, and no forfeiture rate.

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Note 8 - Stock-based Compensation (continued)

a) Warrants (continued)

Below is a table summarizing the warrants issued and outstanding as of December 31, 2022. The warrants outstanding have a weighted average price of $3.80 per share and an aggregate weighted average remaining contractual life of 3.24 years. The warrants exercisable have a weighted average price of $3.88 per share.

Number Outstanding	Number Exercisable	Exercise Price ($)	Weighted Average Remaining Contractual Life (Years)	Proceeds to Company if Exercised $
125,000	125,000	2.47	0.15	308,750
54,000	-	3.05	5.76	164,700
50,000	50,000	3.45	3.17	172,500
125,000	125,000	3.95	4.01	493,750
185,000	185,000	4.90	4.09	906,500
539,000	**485,000**			**2,046,200**

Stock-based compensation expense related to warrants of $84,102 and $701,781 was recorded for the years ended December 31, 2022, and December 31, 2021, respectively. Total remaining unrecognized compensation cost related to non-vested warrants is approximately $35,812 and is expected to be recognized over a period of1.26 years. As of December 31, 2022, the total intrinsic value of warrants was $0.

b) Options

The Company currently has options outstanding under both its 2011 Equity Incentive Plan (the “2011 Plan”) (for option issuances prior to 2016,) and its 2015 Stock Incentive Plan (the “2015 Plan”) (for option issuances commencing in 2016). Effective as of January 1, 2016, no additional awards were or may be made under the 2011 Plan.

The 2015 Plan was adopted by the Board of Directors on August 18, 2015 and approved by the stockholders at an annual meeting held on October 30, 2015. On August 5, 2016, the Board of Directors adopted an amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such Plan by 750,000 shares to an aggregate maximum of 1,750,000 shares, which amendment was approved by the stockholders at an annual meeting held on October 7, 2016. On June 13, 2017, the Board of Directors adopted a subsequent amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such Plan by 750,000 shares to an aggregate maximum of 2,500,000 shares, which amendment was approved by the stockholders at an annual meeting held on September 8, 2017. On June 15, 2018, the Board of Directors adopted a subsequent amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such Plan by 750,000 shares to an aggregate maximum of 3,250,000 shares, which amendment was approved by the stockholders at an annual meeting held on September 7, 2018.

On March 27, 2019, the Board of Directors adopted a subsequent amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such Plan by 1,000,000 shares to an aggregate maximum of4,250,000 shares, which amendment was approved by the stockholders at an annual meeting held on June 14, 2019. On March 31, 2021, the Board of Directors adopted a subsequent amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such Plan by 1,750,000 shares to an aggregate maximum of6,000,000 shares, which amendment was approved by the stockholders at an annual meeting held on June 17, 2021.

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Note 8 - Stock-based Compensation (continued)

b) Options (continued)

On April 4, 2022, the Board of Directors adopted a subsequent amendment to the 2015 Plan to increase the number of shares of common stock available for issuance under such plan by 1,750,000 shares to an aggregate maximum of7,750,000 shares, which amendment was approved by the stockholders at an annual meeting held on June 13, 2022.

The 2015 Plan permits the grant of incentive stock options, non-statutory stock options, restricted stock awards, stock bonus awards, stock appreciation rights, restricted stock units and performance awards. The primary purpose of the 2015 Plan is to enhance the Company's ability to attract and retain the services of qualified employees, officers, directors, consultants and other service providers upon whose judgment, initiative and efforts the successful conduct and development of the Company's business largely depends, and to provide additional incentives to such persons or entities to devote their utmost effort and skill to the advancement and betterment of the Company, by providing them an opportunity to participate in the ownership of the Company that is tied to the Company's performance, thereby giving them an interest in the success and increased value of the Company. The 2015 Plan is administered by the Compensation Committee comprised solely of members of the Board of Directors or by the Board of Directors as a whole.

The following table summarizes the changes in options outstanding of the Company during the years ended December 31, 2022 and December 31, 2021:

	Number of Options	Weighted Average Exercise Price $
Outstanding at December 31, 2020	4,278,619	4.00
Granted	1,090,000	3.41
Exercised	(277,634)	4.19
Expired/Cancelled	(63,467)	3.64
Outstanding at December 31, 2021	5,027,518	3.87
Granted	-	-
Exercised	-	-
Expired/Cancelled	(42,413)	3.43
Outstanding at December 31, 2022	4,985,105	3.87
Exercisable at December 31, 2022	4,495,011	3.93

2022

During the year ended December 31, 2022, no options were granted.

On August 18, 2022, 2,515 Options previously granted to an employee on August 3, 2021 were cancelled and returned as authorized shares under the 2015 Plan upon the resignation of such employee.

On November 18, 2022, 5,000 Options previously granted to an employee on April 13, 2020 were cancelled and returned as authorized shares under the 2015 Plan upon three months following the termination of such employee.

On November 18, 2022, 32,383 Options previously granted to an employee on August 3, 2021 were cancelled and returned as authorized shares under the 2015 Plan upon the resignation of such employee.

On November 18, 2022, 2,515 Options previously granted to an employee on August 3, 2021 were cancelled and returned as authorized shares under the 2015 Plan upon three months following the termination of such employee.

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Note 8 - Stock-based Compensation (continued)

b) Options (continued)

2021

Effective May 20, 2021, the Company granted stock options to purchase40,000 shares of common stock to a Company employee in exchange for services provided to the Company. These options vested on May 20, 2022 and were initially scheduled to expire six years after the grant date, with an exercise price of $3.60 per share. The Company extended the expiration date to ten years after the original grant date. The Company has calculated the estimated fair market value of these options at $73,641, using the Black-Scholes model and the following assumptions: term 3.5 years, stock price $3.50, exercise price $3.60, 76.16% volatility, 0.58% risk free rate, and no forfeiture rate.

During the year ended December 31, 2021, the Company modified a total of3,342,518 options to extend their expiration dates to ten years from the original dates of grant. This resulted in $2,450,349 of expense.

The following table summarizes the amendments to the expiration dates of various options approved during the year ended December 31, 2021. Except as otherwise noted, the expiration dates for all options in the table below were extended from six years to ten years from the original date of grant.

Note	Amendment Date	Equity Incentive Plan	Stock Options #	Grant Date	New Expiration Date	Option Expense $
(i)	Jul 14, 2021	2011	292,000	Jul 23, 2015	Jul 23, 2025	442,273
	Jul 14, 2021	2011	6,367	Mar 20, 2013	Mar 20, 2023	4,151
	Jul 14, 2021	2011	8,151	Sep 2, 2013	Sep 2, 2023	6,009
	Sep 21, 2021	2015	335,000	Apr 13, 2020	Apr 13, 2030	163,945
(ii)	Sep 21, 2021	2015	89,163	Jan 23, 2018	Jan 23, 2028	24,194
(ii)	Sep 21, 2021	2015	308,066	Feb 13, 2017	Feb 13, 2027	127,719
	Nov 3, 2021	2015	760,000	Apr 15, 2016	Apr 15, 2026	984,511
	Nov 3, 2021	2015	15,000	Jun 23, 2016	Jun 23, 2026	19,582
	Nov 3, 2021	2015	50,000	Jan 1, 2017	Jan 1, 2027	32,456
	Nov 3, 2021	2015	387,934	Mar 30, 2017	Mar 30, 2027	224,901
	Nov 3, 2021	2015	615,837	Jan 23, 2018	Jan 23, 2028	213,646
	Dec 8, 2021	2015	425,000	Apr 13, 2020	Apr 13, 2030	180,267
	Dec 8, 2021	2015	10,000	Dec 1, 2020	Dec 1, 2030	5,209
	Dec 8, 2021	2015	40,000	May 20, 2021	May 20, 2031	21,486
			3,342,518			2,450,349

(i) The expiration date of these options were extended from five and a half years to ten years from the original date of grant.

(ii) These options were previously amended on December 16, 2019 and amended again on September 21, 2021.

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Note 8 - Stock-based Compensation (continued)

b) Options (continued)

Effective August 3, 2021, the Company approved the granting of options under the 2015 Plan vesting upon achievement of certain corporate goals (see additional details in Note 10 (h)). Pursuant to this approval, the Company granted stock options to purchase an aggregate of 926,640 shares of common stock to various personnel (including directors, executives, members of management and employees of the Company and/or its subsidiaries) in exchange for services provided to the Company and/or its subsidiaries. These options vest over two years with options to purchase up to 463,328 shares vesting on August 3, 2022, and options to purchase up to 463,312 shares vesting on August 3, 2023, subject to continued service by the optionee, and expire 10 years from the date of grant with an exercise price of $3.40 per share. The actual number of options that are eligible for the time-based vesting is contingent upon the timely achievement of certain pre-determined corporate goals by the Company and/or its subsidiaries as set forth in the grant documents. The Company has calculated the estimated fair market value of these options at $1,811,216, using the Black-Scholes model and the following assumptions: term 5.5 years, stock price $3.31, exercise price $3.40, 69.13% volatility, 1.19% risk free rate, and no forfeiture rate.

Effective September 7, 2021, the Company granted stock options to purchase 50,000 shares of common stock to two employees in exchange for services provided to the Company and/or its subsidiaries. These options vest over two years with 25,000 shares vesting on September 7, 2022, and 25,000 shares vesting on September 7, 2023 subject to continued service by the optionee, and expire 10 years from the date of grant with an exercise price of $3.40 per share. The Company has calculated the estimated fair market value of these options at $98,322, using the Black-Scholes model and the following assumptions: term 5.5 years, stock price $3.32, exercise price $3.40, 68.98% volatility, 1.38% risk free rate, and no forfeiture rate.

Effective October 4, 2021, the Company approved the granting of options under the 2015 Plan vesting upon achievement of certain corporate goals (see additional details in Note 10 (h)). Pursuant to this approval the Company granted stock options to purchase 73,360 shares of common stock to an employee in exchange for services provided to the Company and/or its subsidiaries. These options vest over two years with 36,680 shares vesting on October 4, 2022, and 36,680 shares vesting on October 4, 2023, subject to continued service by the optionee, and expire 10 years from the date of grant with an exercise price of $3.40 per share. The actual number of options that are eligible for the time-based vesting is contingent upon the timely achievement of certain pre-determined corporate goals by the Company and/or its subsidiaries as set forth in the grant documents. The Company has calculated the estimated fair market value of these options at $128,003, using the Black-Scholes model and the following assumptions: term 5.5 years, stock price $3.04 exercise price $3.40, 68.80% volatility, 1.49% risk free rate, and no forfeiture rate.

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Note 8 - Stock-Based Compensation (continued)

b) Options (continued)

Below is a table summarizing the options issued and outstanding as of December 31, 2022, all of which were issued pursuant to the 2011 Plan (for option issuances prior to 2016) or the 2015 Plan (for option issuances commencing in 2016)and which have a weighted average exercise price of $3.87 per share and an aggregate weighted average remaining contractual life of 5.22 years.

Number Outstanding	Number Exercisable	Exercise Price ($)	Weighted Average Remaining Contractual Life (Years)	Proceeds to Company if Exercised $
635,000	635,000	3.25	2.12	2,063,750
2,717	2,717	3.35	0.67	9,102
1,022,587	532,493	3.40	8.32	3,476,796
795,000	795,000	3.60	6.94	2,862,000
1,682,837	1,682,837	4.00	3.76	6,731,348
11,801	11,801	4.35	0.44	51,334
89,163	89,163	4.38	5.07	390,534
50,000	50,000	4.80	4.01	240,000
696,000	696,000	5.00	4.24	3,480,000
4,985,105	**4,495,011**			**19,304,864**

Stock-based compensation expense related to stock options of $l,127,502 and $1,069,605 was recorded for the year ended December 31, 2022 and December 31, 2021 respectively. Total remaining unrecognized compensation cost related to non-vested stock options is approximately $ 287,363 and is expected to be recognized over a period of 0.76 years. As of December 31, 2022, the total intrinsic value of stock options was $nil.

As of December 31, 2022, an aggregate of417,318 shares of common stock remained available for future issuance under the 2015 Plan.

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Note 8 - Stock-Based Compensation (continued)

c) Restricted Stock Units (RSUs)

Below is a table summarizing the RSUs issued and outstanding as of December 31, 2022, all of which were issued pursuant to the 2015 Plan.

	Number of RSUs	Weighted Average Exercise Price $
Outstanding at December 31, 2020	67,500	3.47
Granted	789,500	3.33
Vested	(31,250)	3.55
Cancelled	(15,000)	3.3
Outstanding at December 31, 2021	810,750	3.33
Granted	1,892,102	1.64
Vested	(377,007)	3.33
Cancelled	(62,937)	2.88
Outstanding at December 31, 2022	**2,262,908**	**2.05**

2022

Below is a table summarizing the RSUs granted during the year ended December 31, 2022, all of which were issued pursuant to the 2015 Plan. These RSUs vest equally over periods stated on the dates noted, subject to continued service, and will result in the compensation expense stated. The exception to this is specified in note (iv) which is described in detail below.

Note	Equity Incentive Plan	RSUs #	Grant Date	Vesting Period	First Vesting Date	Second Vesting Date	Third Vesting Date	RSU Expense $
	2015	8,000	Feb 8, 2022	24 Months	Feb 8, 2023	Feb 8, 2024	N/A	22,640
	2015	30,000	Mar 1, 2022	24 Months	Mar 1, 2023	Mar 1, 2024	N/A	84,300
	2015	32,000	Apr 4, 2022	24 Months	Apr 4, 2023	Apr 4, 2024	N/A	94,400
	2015	104,000	Apr 4, 2022	36 Months	Apr 4, 2023	Apr 4, 2024	Apr 4, 2025	306,800
	2015	33,000	Jun 1, 2022	24 Months	Jun 1, 2023	Jun 1, 2024	N/A	80,850
	2015	63,102	Aug 15, 2022	24 Months	Aug 15, 2023	Aug 15, 2024	N/A	126,835
	2015	25,000	Sep 21, 2022	24 Months	Sep 21, 2023	Sep 21, 2024	N/A	42,250
(iii)	2015	1,144,000	Oct 4, 2022	36 Months	Oct 4, 2023	Oct 4, 2024	Oct 4, 2025	1,670,240
(iv)	2015	450,000	Oct 4, 2022	Up to 42 Months	Variable	Variable	Variable	321,078
(v)	2015	3,000	Nov 29, 2022	36 Months	Nov 29, 2023	Nov 29, 2024	Nov 29, 2025	6,450
		1,892,102						**2,755,843**

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Note 8 - Stock-Based Compensation (continued)

c) Restricted Stock Units (RSUs) (continued)

(iii) These RSUs vest upon the achievement of corporate goals focused around product development and commercialization with further time-based vesting, subject to continued service of the award recipient to the Company through the applicable vesting dates. On October 13, 2022, the Compensation Committee of the Board of Directors approved the satisfactory achievement of certain corporate goals previously established by the Compensation Committee, which resulted in the vesting of the rights with respect to an aggregate of 198,275 RSUs. The RSUs are further subject to a three-year time based vesting schedule, vesting in three equal installments on the dates set forth in the table above, and conditioned upon the recipient's continued service through the applicable vesting date. On January 12, 2023, the Compensation Committee of the Board of Directors approved the satisfactory achievement of certain additional corporate goals, which resulted in the vesting of the rights with respect to an aggregate of an additional 424,875 RSUs, subject to the foregoing time-based vesting and conditioned upon the recipient's continued service through the applicable vesting date.

(iv) These RSUs vest upon the share price closing above $5.00 per share for a minimum of ten consecutive trading days within a period of three years from the date of grant, with further time-based vesting in a single installment six months after the timely achievement of the target, if at all, and subject to continued service. The estimated fair value of the RSUs that include a market vesting condition will be measured on the grant date using a Monte Carlo Simulation of a Geometric Brownian Motion stock path model and incorporating the probability of vesting occurring. The estimated fair value of these awards will be recognized over the derived service period (as determined by the valuation model), with such recognition occurring regardless of whether the market condition is met.

(v) The Company granted an aggregate of 3,000 RSUs on November 29, 2022 as an employment inducement award. These RSUs are subject to time-based vesting and subject to the continued service of each recipient.

Below is a table summarizing the RSUs vested during the year ended December 31, 2022, all of which were issued pursuant to the 2015 Plan.

Equity Incentive Plan	RSUs #	Vest Date	Shares Issued	Shares Withheld for Taxes
2015	15,000	Mar 25, 2022	15,000	-
2015	26,250	Apr 13, 2022	21,712	4,538
2015	50,000	May 1, 2022	35,000	15,000
2015	230,102	Aug 3, 2022	191,992	38,110
2015	12,000	Sep 7, 2022	7,038	4,962
2015	19,905	Oct 4, 2022	13,022	6,883
2015	21,750	Nov 1, 2022	12,344	9,406
2015	2,000	Dec 15, 2022	1,181	819
	377,007		**297,289**	**79,718**

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Note 8 - Stock-Based Compensation (continued)

c) Restricted Stock Units (RSUs) (continued)

Below is a table summarizing the RSUs cancelled during the year ended December 31, 2022, all of which were originally issued pursuant to the 2015 Plan.

Equity Incentive Plan	RSUs #	Cancellation Date	RSUs Cancelled
2015	33,000	May 31, 2022	33,000
2015	1,365	Aug 18, 2022	1,365
2015	17,572	Nov 18, 2022	17,572
2015	11,000	Nov 21, 2022	11,000
	62,937		**62,937**

VOLITIONRX LIMITED
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Note 8 - Stock-Based Compensation (continued)

c) Restricted Stock Units (RSUs) (continued)

2021

Below is a table summarizing the RSUs granted during the year ended December 31, 2021, all of which were issued pursuant to the 2015 Plan.

Note	Equity Incentive Plan	RSUs #	Grant Date	Vesting Period	First Vesting Date	Second Vesting Date	Third Vesting Date	RSU Expense $
	2015	5,000	Jan 1, 2021	-	Jan 1, 2021	N/A	N/A	19,450
	2015	30,000	Mar 25, 2021	24 Months	Mar 25, 2022	Mar 25, 2023	N/A	107,700
	2015	150,000	May 1, 2021	36 Months	May 1, 2022	May 1, 2023	May 1, 2024	496,500
(i)	2015	460,191	Aug 3, 2021	24 Months	Aug 3, 2022	Aug 3, 2023	N/A	1,523,232
	2015	38,000	Sep 7, 2021	24 Months	Sep 7, 2022	Sep 7, 2023	N/A	126,160
(ii)	2015	39,809	Oct 4, 2021	24 Months	Oct 4, 2022	Oct 4, 2023	N/A	121,019
	2015	43,500	Nov 1, 2021	24 Months	Nov 1, 2022	Nov 1, 2023	N/A	152,685
	2015	23,000	Dec 15, 2021	24 Months	Dec 15, 2022	Dec 15, 2023	N/A	77,740
		789,500						**2,624,486**

(i) Effective August 3, 2021, the Company approved the granting of RSUs under the 2015 Plan vesting upon achievement of certain corporate goals (see additional details in Note 10 (h)). Pursuant to this approval, the Company granted RSUs of 460,191 shares of common stock to various personnel (including directors, executives, members of management and employees of the Company and/or its subsidiaries) in exchange for services provided to the Company and/or its subsidiaries. The actual number of RSUs that are eligible for the time-based vesting is contingent based upon the timely achievement of certain pre-determined corporate goals by the Company and/or its subsidiaries as set forth in the grant documents as well as continued service by the participant through the applicable vesting date. The RSUs eligible for vesting shall vest over two years with up to 230,102 units vesting on August 3, 2022, and up to 230,089 units vesting on August 3, 2023 and will result in total compensation expense of $1,523,232.

(ii) Effective October 4, 2021, the Company approved the granting of RSUs under the 2015 Plan vesting upon achievement of certain corporate goals (see additional details in Note 10 (h)). Pursuant to this approval, the Company granted RSUs of 39,809 shares of common stock to an employee of the Company and/or its subsidiaries in exchange for services provided to the Company and/or its subsidiaries. The actual number of RSUs that are eligible for the time-based vesting is contingent based upon the timely achievement of certain pre-determined corporate goals by the Company and/or its subsidiaries as set forth in the grant documents as well as continued service by the participant through the applicable vesting date. These RSUs vest over two years with 19,905 units vesting on October 4, 2022, and 19,904 units vesting on October 4, 2023, subject to continued service and will result in total compensation expense of $121,019.

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Note 8 - Stock-Based Compensation (continued)

c) Restricted Stock Units (RSUs) (continued)

Below is a table summarizing the RSUs vested during the year ended December 31, 2021, all of which were issued pursuant to the 2015 Plan.

Equity Incentive Plan	RSUs #	Vest Date	Shares Issued	Shares Withheld for Taxes
2015	5,000	Jan 1, 2021	3,000	2,000
2015	26,250	Apr 13, 2021	21,712	4,538
	31,250		**24,712**	**6,538**

Below is a table summarizing the RSUs cancelled during the year ended December 31, 2021, all of which were originally issued pursuant to the 2015 Plan.

Equity Incentive Plan	RSUs #	Vest Date	RSUs Cancelled
2015	15,000	Dec 31, 2020	15,000
	15,000		**15,000**

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Note 8 - Stock-Based Compensation (continued)

c) Restricted Stock Units (RSUs) (continued)

Below is a table summarizing the RSUs issued and outstanding as of December 31, 2022 of which the last to vest have a remaining contractual life of 3.26 years.

Number Outstanding	Weighted Average Grant date Fair Value $	Weighted Average Remaining Contractual Life (Years)
450,000	0.69	3.26
1,133,000	1.46	1.76
25,000	1.69	1.22
63,102	2.01	1.08
3,000	2.15	1.91
33,000	2.45	0.92
30,000	2.81	0.67
8,000	2.83	0.61
136,000	2.95	0.97
19,904	3.04	0.38
311,152	3.31	0.59
12,000	3.32	0.68
2,000	3.38	0.48
21,750	3.51	0.42
15,000	3.59	0.23
2,262,908		

Stock-based compensation expense related to RSUs of $1,903,054 and $898,910 was recorded in the years ended December 31, 2022, and December 31, 2021, respectively. Total remaining unrecognized compensation cost related to non-vested RSUs is $2,214,593.

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Note 9 - Income Taxes

The Company has estimated net operating losses for the years ended December 31, 2022 and 2021 of $28.6 million and $24.4 million, respectively, available to offset taxable income in future years.

The significant components of deferred income taxes and assets as of December 31, 2022 and December 31, 2021 are as follows:

Net Deferred Tax Liability	**December 31, 2022 $**	**December 31, 2021 $**
Excess of tax over book depreciation and amortization	(46,001)	(8,330)
ROU Asset	(117,134)	(28,657)
Lease Liability	122,279	47,301
Accrued expenses	5,655	1,199
Unrealized Gain/Loss	-	103,106
Capitalized research expenses	1,237,122	-
Stock-based compensation	321,956	186,252
Net Operating Losses carry-forward	28,556,992	24,390,040
Research and development tax credits	769,317	606,729
Gross deferred tax assets	30,850,186	25,297,640
Valuation allowance	(30,850,186)	(25,297,640)
Net deferred tax asset	-	-
Change in Valuation Allowance	(5,552,546)	

Summary Rate Reconciliation	**December 31, 2022 %**	**December 31, 2021 %**
Federal statutory rate	21.0	21.0
State income taxes, net of federal benefit	-	-
Permanent Differences	(0.6)	(4.8)
Stock based compensation	(0.3)	(0.6)
Federal Research & Development Credits	0.7	0.5
Foreign taxes	(0.1)	1.5
Federal Deferred Rate Decrease	0.5	(14.4)
Change in Valuation Allowance	(21.2)	(3.2)
Total	-	-

Disclosure Amounts	**December 31, 2022**
Net Operating Losses - United States	35,072,965
Net Operating Losses - Foreign	90,614,447
Credit Carryforward - United States	-
Credit Carryforward - Foreign	769,317
Increase in Valuation Allowance	5,552,546

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
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Note 10 - Commitments and Contingencies

a) Finance Lease Obligations

In 2016, the Company entered into a real estate capital lease with ING Asset Finance Belgium S.A. ("ING") to purchase a property located in Belgium for €1.12 million, maturing May 2031, with implicit interest of 2.62%. As of December 31, 2022, the balance payable was $482,146.

In 2018, the Company entered into a capital lease with BNP Paribas leasing solutions to purchase a freezer for the Belgium facility for €25,000, maturing January 2022, with implicit interest of 1.35%. The leased equipment is amortized on a straight-line basis over 5 years. As of December 31, 2022, the balance payable was $0. The following is a schedule showing the future minimum lease payments under financing leases by years and the present value of the minimum payments as of December 31, 2022.

2023	$	57,726
2024	$	57,725
2025	$	57,725
2026	$	57,726
2027	$	57,726
Greater than 5 years	$	252,534
Total	$	541,162
Less: Amount representing interest	$	(59,016)
Present value of minimum lease payments	**$**	**482,146**

b) Operating Lease Right-of-Use Liabilities

As of December 31, 2022, operating lease right-of-use assets and liabilities arising from operating leases were $619,392 and $645,254, respectively. During the year ended December 31, 2022, cash paid for amounts included for the measurement of lease liabilities was $245,354 and the Company recorded operating lease expense of $267,434. Our weighted average discount rate is 2.38% and the weighted average remaining lease term is 25 months.

The following is a schedule showing the future minimum lease payments under operating leases by years and the present value of the minimum payments as of December 31, 2022.

2023	$	264,799
2024	$	164,225
2025	$	120,209
2026	$	94,600
2027	$	25,800
Total Operating Lease Obligations	$	669,633
Less: Amount representing interest	$	(24,379)
Present Value of minimum lease payments	**$**	**645,254**

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
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Note 10 – Commitments and Contingencies (continued)

b) Operating Lease Right-of-Use Liabilities (continued)

The Company's office space leases are short term, and the Company has elected under the short-term recognition exemption not to recognize them on the balance sheet. During the year ended December 31, 2022, $76,955 was recognized in short-term lease costs associated with the office space leases in Singapore and Nevada. The annual payments remaining for such short-term office leases as of December 31, 2022, were as follows:

2023	$	27,069
2024 - 2027	$	-
Total Operating Lease Liabilities	**$**	**27,069**

c) Grants Repayable

In 2010, the Company entered into an agreement with the Walloon Region government in Belgium for a colorectal cancer research grant for €1,048,020. Per the terms of the agreement, €314,406 of the grant is to be repaid by installments over the period from June 30, 2014 to June 30, 2023. The Company has recorded the balance of €33,614 to other income in previous years as there is no obligation to repay this amount. In the event that the Company receives revenue from products or services as defined in the agreement, it is due to pay a 6% royalty on such revenue to the Walloon Region. The maximum amount payable to the Walloon Region, in respect of the aggregate of the amount repayable of €314,406 and the 6% royalty on revenue, is twice the amount of funding received As of December 31, 2022, the grant balance repayable was $26,831.

In 2018, the Company entered into an agreement with the Walloon Region government in Belgium for a colorectal cancer research grant for €605,000. Per the terms of the agreement, €181,500 of the grant is to be repaid by instalments over 12 years commencing in 2020. In the event that the Company receives revenue from products or services as defined in the agreement, it is due to pay a 3.53% royalty on such revenue to the Walloon Region. The maximum amount payable to the Walloon Region, in respect of the aggregate of the amount repayable of €181,500 and the 3.53% royalty on revenue, is equal to the amount of funding received. As of December 31, 2022, the grant balance repayable was $107,280.

In 2020, the Company entered into an agreement with the Walloon Region government in Belgium for a research grant for €495,000. Per the terms of the agreement, €148,500 of the grant is to be repaid by installments over 10 years commencing in 2023. In the event that the Company receives revenue from products or services as defined in the agreement, it is due to pay a 2.89% royalty on such revenue to the Walloon Region. The maximum amount payable to the Walloon Region, in respect of the aggregate of the amount repayable of €148,500 and the 2.89% royalty on revenue, is equal to the amount of funding received As of December 31, 2022, the grant balance repayable was $97,799.

In 2020, the Company entered into an agreement with the Walloon Region government in Belgium for a research grant for €929,433. Per the terms of the agreement, €278,830 of the grant is to be repaid by instalments over 15 years commencing in 2022. In the event that the Company receives revenue from products or services as defined in the agreement, it is due to pay a 4.34% royalty on such revenue to the Walloon Region. The maximum amount payable to the Walloon Region, in respect of the aggregate of the amount repayable of €278,830 and the 4.34% royalty on revenue, is equal to the amount of funding received. As of December 31, 2022, the grant balance repayable was $230,392.

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Note 10 – Commitments and Contingencies (continued)

c) Grants Repayable (continued)

As of December 31, 2022, the balance repayable was $462,302 and the annual payments remaining were as follows:

2023	$	49,283
2024	$	26,541
2025	$	34,581
2026	$	42,026
2027	$	45,978
Greater than 5 years	$	263,893
Total Grants Repayable	**$**	**462,302**

d) Long-Term Debt

In 2016, the Company entered into a 7-year loan agreement with Namur Invest for €440,000 with a fixed interest rate of 4.85%, maturing December 2023. As of December 31, 2022, the principal balance payable was $82,659.

In 2016, the Company entered into a 15-year loan agreement with ING for €270,000 with a fixed interest rate of 2.62%, maturing December 2031. As of December 31, 2022, the principal balance payable was $188,806.

In 2017, the Company entered into a 7-year loan agreement with SOFINEX for up to €1 million with a fixed interest rate of 4.50%, maturing September 2024. As of December 31, 2022, €1 million has been drawn down under this agreement and the principal balance payable was $482,954.

In 2018, the Company entered into a 4-year loan agreement with Namur Innovation and Growth for €500,000 with fixed interest rate of 4.00%, maturing June 2022. As of December 31, 2022, the principal balance payable was $0.

In 2019, the Company entered into a 4-year loan agreement with Namur Innovation and Growth for €500,000 with fixed interest rate of 4.80%, maturing September 2024. As of December 31, 2022, the principal balance payable was $279,548.

In 2020, the Company entered into a 10-year loan agreement with Namur Invest for a maximum of €830,000 with fixed interest rate of 4.00%, maturing March 2031. As of December 31, 2022, the amount that has been drawn down under this agreement was €707,599, representing a principal balance payable of $759,419.

On November 23, 2021, the Company entered into a 3 ½ year loan agreement with SOFINEX for a maximum of €450,000 with fixed interest rate of 5.00%, maturing June 2025. As of December 31, 2022, the amount that has been drawn down under this agreement was €450,000, representing a principal balance payable of $442,708.

On February 5, 2022 the Company entered into a 9-month loan agreement with First Insurance Funding for a maximum of $620,549 with fixed interest rate of 3.57%, maturing November 2022. As of December 31, 2022, the principal balance payable was $0.

On August 16, 2022, the Company entered into a 4-year loan agreement with Namur Invest for a maximum of €1,000,000 with fixed interest rate of 6.00%, maturing July 2026. As of December 31, 2022, the amount that has been drawn down under this agreement was €1,000,000, representing a principal balance payable of $1,073,231.

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Note 10 – Commitments and Contingencies (continued)

d) Long-Term Debt (continued)

On November 18, 2022, the Company entered into a 4-year loan agreement with Namur Invest for a maximum of €500,000 with fixed interest rate of 5.45%, maturing December 2027. As of December 31, 2022, the amount that has been drawn down under this agreement was €600,000, representing a principal balance payable of $536,615.

As of December 31, 2022, the total balance for long-term debt payable was $3,845,940 and the payments remaining were as follows:

2023	$ 1,268,528
2024	$ 1,138,227
2025	$ 704,312
2026	$ 480,358
2027	$ 281,602
Greater than 5 years	$ 446,799
Total	$ 4,319,826
Less: Amount representing interest	$ (473,886)
Total Long-Term Debt	**$ 3,845,940**

e) Collaborative Agreement Obligations

In 2018, the Company entered into a research collaboration agreement with the University of Taiwan for a 3-year period for a cost to the Company of up to $2.55 million payable over such period. As of December 31, 2022, $510,000 is still to be paid by the Company under this agreement.

In 2019, the Company entered into a funded sponsored research agreement with the Texas A&M University (“TAMU”) in consideration for the license granted to the Company for a 5-year period for a cost to the Company of up to $400,000 payable over such period. As of December 31, 2022, $0 is still to be paid by the Company under this agreement.

In 2020, the Company entered into a research agreement for the bioinformatic analysis of cell-free DNA fragments from whole-genome sequencing with the Hebrew University of Jerusalem for six months for a cost to the Company of €54,879. Subsequently the parties entered into an amendment to the agreement with an additional cost to the Company of €100,236. In the year ended December 31, 2022, the parties entered into agreements for an additional cost to the Company of €9,000. As of December 31, 2022, $23,018 is still to be paid by the Company under the amended agreement.

On August 2, 2022, the Company entered into a sponsored research agreement with The University of Texas MD Anderson Cancer Center to evaluate the role of neutrophil extracellular traps (“NETs”) in cancer patients with sepsis for a cost to the Company of $346,787. As of December 31, 2022, $346,787 is still to be paid by the Company under this agreement.

As of December 31, 2022, the total amount to be paid for future research and collaboration commitments was approximately $879,805 and the annual payments remaining were as follows:

2023	$ 798,032
2024 - 2027	$ 81,773
Total Collaborative Agreement Obligations	$ 879,805

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Note 10 – Commitments and Contingencies (continued)

f) Other Commitments

Volition Vet

On October 25, 2019, the Company entered into an agreement with TAMU for provision of in-kind services of personnel, animal samples and laboratory equipment in exchange for a non-controlling interest of 7.5% in Volition Vet with an additional 5%, vesting in a year from the date of the agreement, giving TAMU in aggregate, a 12.5% equity interest as of such date. As of December 31, 2022, TAMU has a 12.5 % equity interest in Volition Vet.

Volition Germany

On January 10, 2020, the Company, through its wholly-owned subsidiary Belgian Volition, acquired an epigenetic reagent company, Octamer GmbH ("Octamer"), based in Munich, Germany, and hired its founder for his expertise and knowledge to be passed to Company personnel. On March 9, 2020, Octamer was renamed to Volition Germany GmbH (or "Volition Germany").

In connection with the transaction agreement, the Company entered into a royalty agreement with the founder providing for the payment of royalties in the amount of 6% of net sales of Volition Germany's nucleosomes as reagents to pharmaceutical companies for use in the development, manufacture and screening of molecules for use as therapeutic drugs for a period of five years post-closing.

As of December 31, 2022, $210 is payable under the 6% royalty agreement on sales to date towards the Company's aggregate minimum royalty obligation of $118,055.

Volition America

On November 3, 2020, the Company entered into a professional services master agreement (the "Master Agreement") with Diagnostic Oncology CRO, LLC ("DXOCRO") to conduct a pivotal clinical trial and provide regulatory submission and reimbursement related services. On August 8, 2022, the Company and DXOCRO amended and restated the Master Agreement to expand the scope of DXOCRO's consultant services provided thereunder (the "A&R Master Agreement"). The A&R Master Agreement requires DXOCRO to support development and clinical validation studies for the Company's Nu.Q® product portfolio in the United States, including by conducting large-scale finding studies across multiple sites in the U.S. using Nu.Q® NETs and Nu.Q® Cancer tests to determine clinical utility in sepsis and non-Hodgkin's lymphoma. The Company anticipates DXOCRO's services under the agreement will be completed by the end of the third quarter 2023 at a total cost to the Company of up to $4.2 million The Company's payment obligations accrue upon delivery of projects under the agreement. The Company may terminate the agreement or any project thereunder upon at least 30 days' prior written notice. Unless earlier terminated, the A&R Master Agreement terminates on the later of December 31, 2025 or the date upon which all services have been completed. As of December 31, 2022, $ 264,692 is payable under the A&R Master Agreement, and up $3,435,165 may be payable by Company in future periods for services rendered.

g) Legal Proceedings

There are no legal proceedings which the Company believes will have a material adverse effect on its financial position.

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Note 10 – Commitments and Contingencies (continued)

h) Commitments in Respect of Corporate Goals and Performance-Based Awards

In August 2021 and October 2021, the Compensation Committee of the Board of Directors approved the granting of equity-based awards under the 2015 Plan as well as cash bonuses, vesting upon achievement of certain corporate goals focused around product development and commercialization, to various personnel including directors, executives, members of management, consultants and employees of the Company and/or its subsidiaries.

On June 23, 2022, the Compensation Committee of the Board of Directors approved the achievement of all of the remaining outstanding corporate goals related to the awards in August 2021 and October 2021 resulting in the payment of the cash bonus awards and the vesting of the remaining rights to the equity-based awards, which equity-based awards remain subject to time-based vesting in equal installments on each of August 3, 2022 and August 3, 2023 (with the exception of October 4, 2022 and October 4, 2023 for one award) and the continuous service of the award recipient through the applicable vesting date.

As of December 31, 2022, the Company has paid compensation expense of $737,137 in relation to the July 1, 2022 specified corporate goals based on the actual outcomes related to the prescribed performance targets.

In October 2022, the Compensation Committee of the Board of Directors approved the granting of cash bonuses, payable upon achievement of various corporate goals focused around product development, manufacturing, financing and commercialization, to various personnel including directors, executives, members of management, consultants and employees of the Company and/or its subsidiaries.

Conditional upon the achievement by January 1, 2023 and July 1, 2023 of all specified corporate goals as set forth in the minutes of the Compensation Committee, as well as continued service by the award recipients, the Company at the sole discretion of the Chief Executive Officer and the Chief Financial Officer would pay a cash bonus to such award recipients.

As of December 31, 2022, the Company has accrued compensation expense of $905,856 in relation to the January 1, 2023 and July 1, 2023 specified corporate goals based on the actual outcomes related to the prescribed performance targets.

As discussed in detail in Note 8, -*Stock-Based Compensation,* an aggregate of 1,144,000 RSUs were issued under the 2015 Stock Incentive Plan in connection with the October 2022 grants and an aggregate of 1,000,000 stock options and 500,000 RSUs were issued under the 2015 Stock Incentive Plan in connection with the August 2021 and October 2021 grants.

As of December 31, 2022, the Company has recognized compensation expense of $969,593 in relation to the options vested in 2022 and $630,863 in relation to the options that will vest in 2023. The Company has unrecognized compensation expense of $270,550 to such stock options, based on the outcomes related to the prescribed performance targets on the outstanding awards.

Total Award	Amortised 2022	Amortised 2021	Un-Amortised 2023
$	$	$	$
969,593	580,411	389,182	-
630,863	450,090	180,773	270,550

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 10 – Commitments and Contingencies (continued)

h) Commitments in Respect of Corporate Goals and Performance-Based Awards (continued)

As of December 31, 2022, the Company has recognized compensation expense of $822,149 in relation to the RSUs fully vested in 2022 and $530,930 in relation to RSUs that will vest in 2023. The Company has unrecognized compensation expense of $228,491 to such RSUs, based on the outcomes related to the prescribed performance targets on the outstanding awards.

Total Award	Amortised 2022	Amortised 2021	Un-Amortised 2023
$	$	$	$
822,149	493,207	328,942	-
530,930	379,191	151,739	228,491

As of December 31, 2022, the Company has recognized total compensation expense of $245,861 of which $134,087 in relation to RSUs that will vest in 2023, $65,088 in relation to RSUs that will vest in 2024, and $46,686 in relation to RSUs that will vest in 2025. The Company has unrecognized compensation expense of $1,408,319 in relation to such RSUs, based on the outcomes related to the prescribed performance targets on the outstanding awards.

Vesting Year	Amortised 2022	Un-Amortised
	$	$
2023	134,087	417,327
2024	65,088	470,244
2025	46,686	520,748
	245,861	**1,408,319**

VOLITIONRX LIMITED
Notes to Consolidated Financial Statements
For Years Ended December 31, 2022 and 2021
($ expressed in United States Dollars)

Note 11 - Subsequent Events

Common Stock Issuances and Repurchases

From January 1 to January 19, 2023, the Company raised aggregate net proceeds (net of broker commissions and fees) of approximately $656,000 under the 2022 EDA through the sale of 279,703 shares of its common stock. No additional shares have been sold under the 2022 EDA through March 8, 2023.

On January 5, 2023, the Company purchased from a former officer 13,264 shares of its common stock at $2.39 per share, for a total cost to the Company of $31,772.66. These shares were subsequently retired.

RSU Vesting

On January 12, 2023, the Compensation Committee of the Board of Directors approved the satisfactory achievement of certain corporate goals established by the Compensation Committee on October 4, 2022, which resulted in the vesting of rights with respect to an aggregate of 424,875 RSUs. The RSUs are further subject to a 3-year time based vesting schedule, vesting in three equal installments on each of October 4, 2023, October 4, 2024 and October 4, 2025, respectively, and conditioned upon the recipient's continued service through the applicable vesting date.

On February 8, 2023, 4,000 RSUs previously granted to an employee vested and resulted in the issuance of 2,369 shares of common stock and the remaining 1,631 shares of common stock were withheld as taxes and returned to the 2015 Plan.

On March 1, 2023, 15,000 RSUs previously granted to employees vested and resulted in the issuance of 9,609 shares of common stock. An aggregate of 5,391 shares of common stock were withheld as taxes and returned to the 2015 Plan.

Capital Raise

On February 17, 2023, the Company entered into an underwriting agreement with Newbridge in connection with an underwritten public offering of 4,945,000 shares of the Company's common stock, which includes Newbridge's exercise in full of its overallotment option, pursuant to the Company's 2021 Form S-3. Newbridge purchased the shares from the Company at a price of $1.6275 per share. The offering closed on February 22, 2023. The Company received net proceeds of approximately $8.0 million from the offering before deducting offering expenses payable by the Company.

Commercial Product Launches

On January 12, 2023, the Company announced the availability of its Nu.Q® Vet Cancer Test through the IDEXX Laboratories, Inc. reference laboratory network in the U.S.

On February 16, 2023, the Company announced that its Nu.Q® Vet Cancer Test was available for pre-order to veterinarians at the point of care through Heska.

END NOTES TO FINANCIALS

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by our company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our Principal Executive and Principal Financial Officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management carried out an evaluation under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer have concluded that, as of December 31, 2022, our disclosure controls and procedures were not effective because of material weakness in our internal control over financial reporting relating to the segregation of duties in some areas of finance.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). 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 accounting principles U.S. GAAP.

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.

Under the supervision and with the participation of management, including the Principal Executive Officer and Principal Financial Officer, the Company conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of December 31, 2022, using the criteria established in "*Internal Control - Integrated Framework (2013)*" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

During the year ended December 31, 2022, our management, with oversight from our audit committee, implemented the following remediation steps to address and mitigate the underlying deficiencies which gave rise to the material weaknesses and to improve our internal control over financial reporting:

- hired specialists in human resources and information technology to recommend and implement relevant policies and processes that will strengthen the control environment;
- changed organizational reporting lines and reallocated certain responsibilities to improve segregation of duties around payroll;
- engaged additional resources to help us assess, document, design and implement control activities related to internal control over financial reporting; and
- implemented additional review procedures at each month end close.

During 2023, we intend to take additional measures to strengthen certain processes we have identified which we believe once implemented in conjunction with the completed actions above will mitigate and remedy this weakness.

We also intend to take additional steps to continue to strengthen the control environment. Such measures include but may not be limited to:

- hiring additional finance resources;
- strengthening our internal processes and reviews, including formal documentation thereof; and
- preparation of risk-control matrices to identify key risks and develop and document policies to mitigate those risks.

As we continue to evaluate and test the remediation plan outlined above, we may also identify additional measures to address the material weaknesses or modify certain of the remediation procedures described above. We may also implement additional changes to our internal control over financial reporting as may be appropriate in the course of remediating the material weakness. Management, with the oversight of our audit committee, will continue to take steps necessary to remedy the material weakness to reinforce the overall design and capability of our control environment.

Changes in Internal Control over Financial Reporting

The Audit Committee of the Board of Directors meets regularly with our financial management, and with the independent registered public accounting firm engaged by us. Internal accounting controls and the quality of financial reporting are discussed during these meetings. The Audit Committee has discussed with the independent registered public accounting firm matters required to be discussed by the auditing standards adopted or established by the Public Company Accounting Oversight Board ("PCAOB"). In addition, the Audit Committee and the independent registered public accounting firm have discussed the independent registered public accounting firm's independence from the Company and its management, including the matters in the written disclosures required by PCAOB Rule 3526 *"Communicating with Audit Committees Concerning Independence."*

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than those described above.

The Company is not required to include, and does not include an auditor's attestation report under SEC Rules. Consequently, the Company's registered public accounting firm has not attested to management's reports on the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Effective March 1, 2023, Singapore Volition entered into an employment agreement with Cameron Reynolds, the Company's Chief Executive Officer (the "Reynolds Employment Agreement"), which supersedes and replaces in its entirety the Consulting Services Agreement between Singapore Volition and PB Commodities Pte. Ltd., a Singapore corporation ("PB Commodities"), dated December 1, 2020, pursuant to which PB Commodities made Mr. Reynolds' services available to the Company.

The Reynolds Employment Agreement continues until terminated by either party providing not less than six months' prior notice. In exchange for his services, Mr. Reynolds shall receive, among other things, (i) an annual base salary of $450,300 from Singapore Volition, paid in equal monthly installments, and (ii) a lump sum severance payment if terminated by Singapore Volition without cause equal to the salary that he would have received between the date of termination and the completion of a six-month notice period.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required under this Item is incorporated by reference from our definitive proxy statement related to our 2023 Annual Meeting of Stockholders, or the Proxy Statement, to be filed pursuant to Regulation 14A, on or before May 1, 2023.

ITEM 11. EXECUTIVE COMPENSATION

The information required under this Item is incorporated herein by reference from the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required under this Item is incorporated herein by reference from the Proxy Statement.

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

The information required under this Item is incorporated herein by reference from the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this Item is incorporated herein by reference from the Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Report:

1. *Financial Statements.* Included in Part II, Item 8 of this Report and are incorporated by reference herein.

2. *Financial Statement Schedules.* Financial statement schedules are omitted because they are not applicable, or the required information is shown in the financial statements or notes thereto.

3. *Exhibits.*

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	Share Purchase Agreement, by and between Singapore Volition and ValiRX, dated September 22, 2010.	8-K/A	000-30402	2.1	5/8/12	
2.2	Supplementary Agreement to the Share Purchase Agreement, by and between Singapore Volition and ValiRX, dated June 9, 2011.	8-K/A	000-30402	10.15	1/11/12	
2.3	Share Exchange Agreement by and among Standard Capital Corporation, the controlling shareholders of Standard Capital Corporation and Singapore Volition, dated September 26, 2011.	8-K	000-30402	2.1	9/29/11	
2.4	Agreement, Consent and Waiver by and between Standard Capital Corporation and its Shareholders, dated September 27, 2011.	8-K/A	000-30402	10.28	4/5/12	
3.1	Second Amended and Restated Certificate of Incorporation, as currently in effect.	8-K	001-36833	3.1	10/11/16	
3.2	Amended and Restated Bylaws, as currently in effect.	S-8	333-208512	4.2	12/11/15	
4.1	Description of Capital Stock.	10-K	001-36833	4.1	2/20/20	
10.1	Non-Exploitation and Third-Party Patent License Agreement, by and among ValiBio SA, ValiRX and The Walloon Region, dated December 17, 2009.	8-K/A	000-30402	10.6	2/24/12	
10.2#	Employment Agreement, by and between VolitionRx and Jason Terrell MD, dated December 29, 2015.	10-K	001-36833	10.24	3/11/16	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.3#	2011 Equity Incentive Plan dated November 17, 2011.	8-K	000-30402	4.1	11/18/11	
10.3(a)#	Form Stock Option Agreement.	8-K	000-30402	4.2	11/18/11	
10.3(b)#	Form Stock Award Agreement for Restricted Stock under the 2011 Equity Incentive Plan.	8-K	000-30402	4.3	11/18/11	
10.4#	2015 Stock Incentive Plan, as amended.	8-K	001-36833	10.1	6/14/22	
10.4(a)#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.2	10/14/16	
10.4(b)#	Form of Notice of Restricted Stock Award and Restricted Stock Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.3	10/14/16	
10.4(c)#	Form of Notice of Stock Bonus Award and Stock Bonus Award Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.4	10/14/16	
10.4(d)#	Form of Notice of Stock Appreciation Right Award and Stock Appreciation Right Award Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.5	10/14/16	
10.4(e)#	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.6	10/14/16	
10.4(f)#	Form of Notice of Performance Shares Award and Performance Shares Agreement under the 2015 Stock Incentive Plan.	S-8	333-214118	10.7	10/14/16	
10.5#	Independent Director Agreement.	10-Q	001-36833	10.33	5/12/15	
10.6	Real Estate Capital Lease Agreement, by and between Belgian Volition and ING Asset Finance Belgium S.A., dated October 4, 2016 (English translation of French original).	8-K	001-36833	10.1	10/31/16	
10.7	Deed of Sale to the Sale Agreement, by and between Belgian Volition and Gerard Dekoninck S.A., dated October 25, 2016 (English translation of French original).	8-K	001-36833	10.2	10/31/16	
10.8#	Employment Agreement, by and between Volition Diagnostics UK Limited and Jacob Micallef, dated March 7, 2017.	10-K	001-36833	10.28	3/10/17	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.9#	Employment Agreement, by and between Volition Diagnostics UK and Martin Faulkes, dated March 7, 2017.	10-K	001-36833	10.30	3/10/17	
10.10	Unsecured Credit Agreement, by and among VolitionRx, Belgian Volition and SOFINEX (English translation of French original), dated September 20, 2017.	8-K	001-36833	10.1	9/21/17	
10.11	Clinical Study Agreement, by and between Volition America and the Regents of the University of Michigan, dated July 17, 2017.	10-Q	001-36833	10.1	11/9/17	
10.11(a)	Amendment #1 to Clinical Study Agreement, by and between Volition America, Inc. and the Regents of the University of Michigan, dated February 17, 2020.	10-K	001-36833	10.22	2/20/20	
10.12#	Warrant to Purchase Common Stock, by and between VolitionRx and Jason Terrell MD, dated March 20, 2013; First Amendment to Warrant Agreement, dated February 14, 2017; and Second Amendment to Warrant Agreement, dated July 1, 2019.	S-3	333-236335	4.3	2/7/20	
10.13	Equity Distribution Agreement, by and among VolitionRx, Oppenheimer & Co. Inc. and Cantor Fitzgerald & Co., dated November 12, 2020.	10-Q	001-36833	1.1	11/12/20	
10.14#	Consulting Services Agreement, by and between Singapore Volition and PB Commodities Pte. Ltd. (Cameron Reynolds), dated December 1, 2020.	10-Q	001-36833	10.1	11/12/20	
10.15#†	Common Stock Warrant issued by VolitionRx to Gael Forterre, dated January 1, 2021.	10-K	001-36833	10.18	3/22/21	
10.16#†	Singapore Volition Pte. Limited Employment Agreement, by and between Singapore Volition and Terig Hughes, dated January 27, 2021 and effective February 1, 2021, including the form of Common Stock Warrant attached as Schedule 2.	10-K	001-36833	10.19	3/22/21	
10.17#†	Volition America, Inc. Employment Agreement, by and between Volition America and Gael Forterre, dated February 1, 2021.	10-K	001-36833	10.20	3/22/21	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.18#	Volition Veterinary Diagnostics Development, LLC Employment Agreement Chief Executive Officer, by and between Volition Veterinary Diagnostics Development and Salvatore Thomas Butera, dated March 25, 2021.	10-Q	001-36833	10.6	5/11/21	
10.19	Equity Distribution Agreement, by and among VolitionRx, Oppenheimer & Co. Inc. and Cantor Fitzgerald & Co., dated September 24, 2021.	S-3	333-259783	1.2	9/24/21	
10.20#	Employment Agreement, by and between Volition America and Gaetan Michel, dated September 15, 2021.	10-Q	001-36833	10.1	11/10/21	
10.21#†	Consulting Services Agreement, by and between Volition Global and 3F Management SPRL (Gaetan Michel), dated September 15, 2021.	10-Q	001-36833	10.2	11/10/21	
10.22#	Employment Agreement, by and between Volition Diagnostics and Nick Plummer, dated August 23, 2021.	10-Q	001-36833	10.3	11/10/21	
10.23†	License and Supply Agreement between Belgian Volition and Heska Corporation, dated March 28, 2022.	10-Q	001-36833	10.1	5/11/22	
10.24	Equity Distribution Agreement, dated May 20, 2022, by and between VolitionRx Limited and Jefferies LLC.	8-K	001-36833	1.1	5/20/22	
10.25	Underwriting Agreement, dated July 29, 2022, by and between VolitionRx Limited and Newbridge Securities Corporation.	8-K	001-36833	1.1	8/2/22	
10.26	Underwriting Agreement, dated February 17, 2023, by and between VolitionRx Limited and Newbridge Securities Corporation.	8-K	001-36833	1.1	2/21/23	
10.27#	Singapore Volition Pte. Limited Employment Agreement – Group Chief Executive Officer, dated March 13, 2023, by and between Singapore Volition and Cameron Reynolds.					X
21.1	List of Subsidiaries.					X
23.1	Consent of independent registered public accounting firm.					X
24.1	Power of Attorney (included on the signature page of this Report).					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.					X
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					
10.1 INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					X

# Indicates a management contract or compensatory plan or arrangement.

† Portions of this exhibit are redacted pursuant to Item 601(a)(6) and/or Item (b)(10)(iv) under Regulation S-K. The registrant agrees to furnish supplementally any omitted schedules to the SEC upon request.

* The certifications attached as Exhibit 32.1 accompany this Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the registrant for purposes of Section 18 of the Exchange Act and are not to be incorporated by reference into any of the registrant's filings under the Securities Act or the Exchange Act, irrespective of any general incorporation language contained in any such filing.

ITEM 16. FORM 10-K SUMMARY

None.

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SIGNATURES

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

VOLITIONRX LIMITED

Dated: March 15, 2023

By: */s/ Cameron Reynolds*
Cameron Reynolds
President, Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Cameron Reynolds and Rodney Rootsaert, and each or either of them, acting individually, his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or his, her or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

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

Signature	Title	Date
/s/ Cameron Reynolds Cameron Reynolds	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2023
/s/ Terig Hughes Terig Hughes	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 15, 2023
/s/ Dr. Martin Faulkes Dr. Martin Faulkes	Director	March 15, 2023
/s/ Guy Innes Guy Innes	Director	March 15, 2023
/s/ Dr. Alan Colman Dr. Alan Colman	Director	March 15, 2023
/s/ Dr. Phillip Barnes Dr. Phillip Barnes	Director	March 15, 2023
/s/ Dr. Edward Futcher Dr. Edward Futcher	Director	March 15, 2023
/s/ Kim Nguyen Kim Nguyen	Director	March 15, 2023
/s/ Richard Brudnick Richard Brudnick	Director	March 15, 2023
/s/ Mickie Henshall Mickie Henshall	Director	March 15, 2023

SINGAPORE VOLITION PTE. LIMITED
EMPLOYMENT AGREEMENT
GROUP CHIEF EXECUTIVE OFFICER

This Employment Agreement ("Agreement") is dated March 13, 2023 ("Execution Date") and is effective from March 01, 2023 (the "Effective Date") by and between Singapore Volition Pte. Limited, a Singapore corporation ("Company" or "We") and Cameron Reynolds ("Employee" or "You"). The Company and Employee are sometimes referred to herein individually as a "Party" or collectively as the "Parties.

WITNESSETH:

WHEREAS, the Company desires that Employee be employed by the Company, and render services to the Company and its subsidiaries and affiliates, and Employee is willing to be so employed and to render such services, all upon the terms and subject to the conditions contained herein.

WHEREAS, in order to ensure a harmonious ongoing business working relationship among themselves with respect to the conduct pursuant to the terms and conditions outlined in this Employment Agreement, the Parties desire to enter into this Agreement.

AGREEMENT:

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. EMPLOYMENT.

(a) This agreement supersedes and replaces in its entirety the existing Consulting Services Agreement between the Company and PB Commodities Pte. Ltd. dated December 1, 2020 (the "PB Consultancy Agreement"), which is hereby terminated upon mutual agreement and is of no further force and effect as from the Effective Date (other than the provisions expressly surviving termination under Section 4(e) of the PB Consultancy Agreement).

(b) Subject to and upon the terms and conditions contained in this Agreement, the Company hereby agrees to employ Employee and Employee agrees to be employed by the Company as of the Effective Date, and, to render to the Company, its affiliates and/or subsidiaries the services described in Section 3 hereof.

2. TERM. Employee's employment under this Agreement shall commence as of the Effective Date hereof and shall continue until terminated in accordance with the provisions of this Agreement (the "Employment Term").

3. DUTIES.

(a) Group Chief Executive Officer. Employee shall serve as the Group Chief Executive Officer of the Company, reporting directly to the Board of Directors (the "Board") of VolitionRx Limited ("VolitionRx"). Employee shall be responsible for the performance of such duties, functions and responsibilities as typically carried out by the Chief Executive Officer of a US listed company, as reasonably and lawfully directed by the Board.

(b) Company Policies. Employee agrees to abide by all bylaws and policies of the Company and its affiliates and/or subsidiaries promulgated from time to time by the Company and/or such entities as well as all laws, statutes and regulations.

(c) Place of Work. The normal place of work for the Employee shall be from his home, or from such other location as mutually agreed upon between the Company and the Employee. The Employee will be required to be available for domestic and international travel as the Company's business reasonably requires.

4. BEST EFFORTS. Employee agrees to devote his full business time and attention, as well as his best efforts, energies and skill, to the discharge of the duties and responsibilities attributable to his position.

5. COMPENSATION. For the duration of the Employment Term and as compensation for his services and covenants hereunder, the Employee shall receive:

(a) Salary. Employee's base salary shall be Four Hundred and Fifty Thousand Three Hundred U.S. Dollars (US$450,300) per year ("Base Salary"). The Base Salary shall be payable in equal monthly instalments in U.S Dollars in accordance with the Company's standard payroll practices and policies for employees. The Base Salary shall be reviewed annually, and any increases will be approved by the VolitionRx Board of Directors or its Compensation Committee, and the Board of the Company.

(b) Incentive Plans. During the Employment Term, the Employee shall also be eligible to participate in other employee incentive plans of VolitionRx and/or the Company, if any. The criteria for determining the amount of any allocations to the Employee under such incentive plans for employees, including the criteria for determining the amount of any award, and the conditions that must be satisfied to entitle Employee to receive such award for any year during the Employment Term of this Agreement shall be determined, in the sole discretion of the VolitionRx Board of Directors, its Compensation Committee or the Company's Board, as applicable.

(c) Health Insurance. During the Employment Term, the Company shall directly pay or reimburse the Employee for the premiums of a health insurance policy for the Employee and his dependents, up to a maximum of One Thousand Five Hundred U.S. Dollars (US$1,500) per month, until such time as the Company establishes a health and medical insurance benefits program in which the Employee is entitled to participate. If Employee's employment terminates, with or without any reason, the Company shall have no obligation to continue to directly pay or reimburse the costs of the health insurance policy for the Employee. Reimbursement shall be subject to the production of receipts or other appropriate evidence of payment.

(d) Pension. During the Employment Term, the Company will pay an amount towards the Employee's personal pension scheme (currently 3% of the aggregate of the Employee's Base Salary and any cash bonus awards) which shall be payable in cash as a separate allowance to be paid together with his monthly salary.

6. EXPENSES. Employee shall be reimbursed for business expenses incurred by him which are reasonable and necessary for Employee to perform his duties under this Agreement, subject to the production of receipts or other appropriate evidence of payment. In claiming expenses, the Employee shall comply with the Company's Travel and Expenses Policy or any other Expenses Policies implemented by the Company (as amended from time to time), copies of which will be provided.

7. EMPLOYEE BENEFITS.

(a) Paid Time Off (PTO). Employee shall be entitled to twenty-five (25) days paid vacation (excluding public holidays) on an annual basis in accordance with the Company's policies, as may be established from time to time by the Company for its employees, which shall be taken at such time or times as shall be mutually agreed upon by the Parties. The Employee shall not carry forward any accrued but untaken vacation entitlement to a subsequent calendar year, except as set out in the holiday policy of the Company's Employee Handbook (as amended from time to time), a copy of which will be provided.

(b) Insurance. During the Employment Term, Employee shall be entitled to participate in such group term insurance, disability insurance, health and medical insurance benefits, life insurance and retirement plans or programs as are from time to time generally made available to executive employees of the Company pursuant to the policies of the Company. The Employee's eligibility to participate in the aforementioned schemes is subject to the Employee complying with the conditions attendant to coverage by such plans, and the Employee shall comply with and be entitled to benefits only to the extent former employees are eligible to participate in such arrangements pursuant to the terms of the arrangement, any insurance policy associated therewith and applicable law, and, further, shall be entitled to benefits only in accordance with the terms and conditions of such plans. The Company may withhold from any benefits payable to Employee all taxes and amounts as shall be permitted or required to be withheld pursuant to any applicable law, rule or regulation. Furthermore, the Company may amend, modify or rescind any benefit plan or program and change contribution amounts to benefit costs without notice in its discretion. Employee shall further be subject to the indemnification by-laws policies and/or procedures applicable to senior officers of the Company and shall be included in the Directors & Officers insurance policies maintained by VolitionRx.

8. DEATH AND DISABILITY.

(a) Death. The Employment Term shall terminate on the date of Employee's death, in which event the Company shall, within thirty (30) days of the date of death, pay to his estate, any unpaid Base Salary earned up to the date of death plus an additional lump-sum payment equal to two (2) monthly payments under his Base Salary, outstanding reimbursable expenses, accrued and unused vacation time, and any vested benefits expressly payable in accordance with the applicable plan or program owing to Employee through to the date of Employee's death. Employee will not be entitled to any other compensation upon termination of his employment pursuant to this Section 8(a).

(b) Disability. To the extent permitted by law, the Employment Term shall terminate upon Employee's Disability. For purposes of this Agreement, "Disability" shall mean that Employee is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 6 months, or 150 non-consecutive days in any twelve (12) month period. The existence of a Disability shall be determined by a qualified physician nominated by the Company in consultation with Employee. In case of such termination, Employee shall be entitled to receive his unpaid Base Salary earned up to the date of the Company's determination of Employee's Disability, outstanding reimbursable expenses and accrued and unused vacation or PTO time, and any vested benefits expressly payable in accordance with the applicable plan or program owing to Employee through the date of termination, which amounts shall be paid within thirty (30) days of the date of the Company's determination of Employee's Disability. The Employee will not be entitled to any other compensation upon termination of his employment pursuant to this Section 8(b).

9. TERMINATION OF EMPLOYMENT.

(a) Termination With Cause By Company. The Company may terminate this Agreement at any time during the Employment Term for "Cause" upon written notice to Employee, upon which termination shall be effective immediately. For purposes of this Agreement, "Cause" means the following:

i. Willful and material failure to adhere to the Company's and/or its affiliates' and subsidiaries' bylaws or written policies, or lawful directives of the Board of Directors of VolitionRx, provided Employee shall be given no less than fifteen (15) business days to cure the same after written notice of any failure, if curable in the reasonable discretion of the Company;

ii. Misappropriation (or attempted misappropriation) of any non-trivial Company and/or its affiliates and/or subsidiaries property or funds;

iii. Conviction of, or the entry of a guilty plea or plea of no contest with respect to, any felony involving moral turpitude; and

iv. Gross misconduct.

(b) Other Termination By Company. The Company may terminate this Agreement at any time during the Employment Term without "Cause" either (i) upon six (6) months written notice to Employee; or (ii) if less than six (6) months written notice then subject to the payment of a lump sum equal to the balance of the Employee's Base Salary that would otherwise have been received between the date of termination and the completion of the six (6) month notice period (which lump sum shall be payable upon receipt by the Company of a satisfactory release from Employee).

(c) Termination By Employee. Employee may terminate this Agreement at any time by providing the Company six (6) months written notice, with or without any reason.

(d) Compensation upon Termination. Upon termination of the Agreement pursuant to this Section 9, Employee shall be entitled to all accrued and unpaid compensation earned as of the date of termination, including Base Salary, outstanding reimbursable expenses, accrued and unused vacation or PTO time, and any vested benefits expressly payable in accordance with the applicable plan or program. Employee shall also receive any awarded and unpaid bonus for a prior completed year, if not yet paid as of the termination date, within 30 days of the termination date.

10. DISCLOSURE OF TRADE SECRETS AND OTHER PROPRIETARY INFORMATION; RESTRICTIVE COVENANTS.

(a) Employee acknowledges that he is prohibited from directly or indirectly disclosing any confidential information about the Company, its affiliates and/or subsidiaries or companies with whom the Company, its affiliates and/or subsidiaries do business, including but not limited to trade secrets, formulas, and financial information, to any party who is not a director, officer or authorized agent of the Company or its subsidiaries and affiliates. The Company will provide Employee with valuable confidential information belonging to the Company or its subsidiaries or its affiliates above and beyond any confidential information previously received by Employee and will associate Employee with the goodwill of the Company or its subsidiaries or its affiliates above and beyond any prior association of Employee with that goodwill. In return, Employee promises never to disclose or misuse such confidential information and never to misuse such goodwill.

(b) Employee will not, during the Employment Term and for a period of six (6) months thereafter, on his behalf or on behalf of any other business enterprise, directly or indirectly, under any circumstance other than at the direction and for the benefit of the Company, its affiliates and/or subsidiaries, (i) solicit for employment or hire any person employed by the Company or any of its subsidiaries or affiliates, or (ii) call on, solicit, or take away any person or entity who was a customer of the Company or any of its subsidiaries or affiliates during Employee's employment with the Company, in either case for a business that is competitive with the business of the Company, its affiliates and/or subsidiaries. This restriction shall not prevent Employee from soliciting or doing business with any customer with whom he had a pre-existing business relationship and which is identified to the Company in a written list provided by Employee at termination of employment.

(c) It is expressly agreed by Employee that the nature and scope of each of the provisions set forth above are reasonable and necessary. If, for any reason, any aspect of the above provisions as it applies to Employee is determined by a court of competent jurisdiction to be unreasonable or unenforceable under applicable law, the provisions shall be modified to the extent required to make the provisions enforceable. Employee acknowledges and agrees that his services are of unique character and expressly grants to the Company or any subsidiary or affiliate of the Company or any successor of any of them, the right to enforce the above provisions through the use of all remedies available at law or in equity, including, but not limited to, injunctive relief.

11. COMPANY PROPERTY.

(a) Any patents, inventions, discoveries, applications, processes, models or financial statements designed, devised, planned, applied, created, discovered or invented by Employee during the Employment Term, regardless of when reduced to writing or practice, which pertain to any aspect of the Company's or its subsidiaries' or affiliates' business as described above shall be the sole and absolute property of the Company, and Employee shall promptly report the same to the Company and promptly execute any and all documents that may from time to time reasonably be requested by the Company to assure the Company the full and complete ownership thereof.

(b) All records, files, lists, including computer generated lists, drawings, documents, equipment and similar items relating to the Company's, its affiliates' and/or subsidiaries' business which Employee shall prepare or receive from the Company shall remain the Company's, its affiliates' and/or subsidiaries' sole and exclusive property. Upon termination of this Agreement, Employee shall promptly return to the Company all property of the Company, its affiliates and/or subsidiaries in his possession. Employee may retain copies of documents evidencing his terms of employment, compensation, or related to his status as an equity holder of the Company.

12. EQUITABLE RELIEF. It is mutually understood and agreed that Employee's services are special, unique, unusual, extraordinary and of an intellectual character giving them a peculiar value, the loss of which cannot be reasonably or adequately compensated in damages in an action at law. Accordingly, in the event of any breach of this Agreement by Employee, including, but not limited to, the breach of any of the provisions of Sections 10 or 11 hereof, the Company shall be entitled to equitable relief by way of injunction or otherwise in addition to any damages which the Company may be entitled to recover. In the event of any breach of this Agreement by Company the Employee shall be entitled to equitable relief by way of injunction or otherwise in addition to any damages which the Employee may be entitled to recover.

13. APPLICABLE LAW AND DISPUTES. Unless otherwise stated, this Agreement will be governed by and construed in accordance with the laws of the Republic of Singapore. All disputes concerning this Agreement will first be negotiated between the Parties in good faith. If the Parties are unable to settle any difference, dispute, conflict or controversy (a "**Dispute**"), which arises out of or in connection with this Agreement or its performance, including without limitation any dispute regarding its existence, validity, termination of rights or obligations of any party, then such Dispute shall be referred to and finally resolved by arbitration in Singapore in accordance with the Arbitration Rules of the Singapore International Arbitration Centre (**"SIAC"**) in force at the time of referral of the Dispute (the "**Rules**"). The place of arbitration shall be Singapore and the proceedings shall be conducted in the English language. There shall be a single arbitrator and the appointing authority shall be the Chairman of the SIAC.

14. NOTICE. Except as otherwise expressly provided, any notice, request, demand or other communication permitted or required to be given under this Agreement shall be in writing, shall be deemed conclusively to have been given: (a) upon receipt, when delivered personally; (b) upon receipt when sent by facsimile or email delivery of a ".pdf" format data file (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party; (c) on the third business day following the day timely deposited with Federal Express (or other equivalent international courier), with the cost of delivery prepaid or for the account of the sender; (d) on the seventh business day following the day duly sent by certified or registered mail, postage prepaid; or (e) when otherwise actually received by the addressee on a business day (or on the next business day if received after the close of normal business hours or on any non-business day).

15. INTERPRETATION; HEADINGS. The parties acknowledge and agree that the terms and provisions of this Agreement have been negotiated, shall be construed fairly as to all parties hereto, and shall not be construed in favor of or against any party. The section headings contained in this Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Agreement.

16. SUCCESSORS AND ASSIGNS; ASSIGNMENT; INTENDED BENEFICIARIES. Neither this Agreement, nor any of Employee's rights, powers, duties or obligations hereunder, may be assigned by Employee. This Agreement shall be binding upon and inure to the benefit of Employee and his heirs and legal representatives and the Company and its successors. Successors of the Company shall include, without limitation, any corporation or corporations acquiring, directly or indirectly, all or substantially all of the assets of the Company, whether by merger, consolidation, purchase, lease or otherwise, and such successor shall thereafter be deemed "the Company" for the purpose hereof.

17. NO WAIVER BY ACTION. Any waiver or consent from the Company respecting any term or provision of this Agreement or any other aspect of the Employee's conduct or employment shall be effective only in the specific instance and for the specific purpose for which given and shall not be deemed, regardless of frequency given, to be a further or continuing waiver or consent. The failure or delay of the Company at any time or times to require performance of, or to exercise any of its powers, rights or remedies with respect to, any term or provision of this Agreement or any other aspect of the Employee's conduct or employment in no manner (except as otherwise expressly provided herein) shall affect the Company's right at a later time to enforce any such term or provision.

1 8 . COUNTERPARTS; ELECTRONIC SIGNATURE; JURISDICTION; AMENDMENTS; ENTIRE AGREEMENT; SEVERABILITY; SURVIVAL OF TERMS.

(a) This Agreement may be executed in two (2) counterpart copies, each of which may be executed by one of the Parties hereto, but all of which, when taken together, shall constitute a single agreement binding upon all of the Parties hereto.

(b) For convenience, this Agreement may be signed electronically and/or electronically transmitted in Portable Document Format (PDF), in one or more copies, each of which shall be deemed to be an original and all of which shall constitute one and the same instrument. The Parties acknowledge that the exchange of the Agreement signed electronically or signed manually by one or both Parties but transmitted in PDF format shall have the same legal value and probative force as the exchange of original signatures.

(c) Each and every modification and amendment of this Agreement shall be in writing and signed by the parties hereto, and any waiver of, or consent to any departure from, any term or provision of this Agreement shall be in writing and signed by each affected party hereto.

(d) This Agreement contains the entire agreement of the parties and supersedes all prior representations, agreements and understandings, oral or otherwise, between the parties with respect to the matters contained herein, including but not limited to any written offer letter or letter agreement concerning employment. In the event of any conflict, the terms of this Agreement shall control.

(e) The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(f) Sections 10 through 19 shall survive any termination of this Agreement and the termination of Employee's employment.

19. TAX AND DEDUCTION. All payments to Employee pursuant to this Agreement are subject to applicable tax, withholding and deduction requirements based on the country of Employee's service.

[Signature page follows.]

SIGNATURES

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date set forth above.

By:

("**COMPANY**")
Singapore Volition Pte. Limited

/s/ Jasmine Kway
By: Jasmine Kway
Its: Chief Executive Officer

By:

("**EMPLOYEE**")
Cameron Reynolds

/s/ Cameron Reynolds
By: Cameron Reynolds

[*Signature Page to Singapore Volition Pte. Limited Employment Agreement – Group Chief Executive Officer*]

EXHIBIT 21.1

SUBSIDIARIES OF VOLITIONRX LIMITED

Name of Subsidiary	State or other Jurisdiction of Incorporation or Organization
Singapore Volition Pte. Limited *(100% subsidiary of VolitionRx Limited)*	Singapore
Belgian Volition SRL *(100% subsidiary of Singapore Volition Pte. Limited)*	Belgium
Volition Diagnostics UK Limited *(100% subsidiary of Belgian Volition SRL)*	United Kingdom
Volition America, Inc. *(100% subsidiary of Belgian Volition SRL)*	Delaware
Volition Veterinary Diagnostics Development LLC. (*87.5% subsidiary of Belgian Volition SRL)*	Texas
Volition Germany GmbH *(100% subsidiary of Belgian Volition SRL)*	Germany
Volition Global Services SRL *(100% subsidiary of VolitionRx Limited)*	Belgium

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee
VolitionRx Limited

As independent registered public accountants, we hereby consent to the incorporation by reference of our report dated March 15, 2023, contained in this annual report on Form 10-K with respect to the consolidated financial statements of VolitionRx Limited, in its registration statements on Form S-3 (Registration Statement Nos. 333-195213, 333-227248, 333-227731, 333-236335 and 333-259783) and its registration statements on Form S-8 (Registration Statement Nos. 333-208512, 333-214118, 333-221054, 333-227565, 333-236336, 333-258133 and 333-267692).

/s/ Sadler, Gibb & Associates, LLC

Sadler, Gibb & Associates, LLC
March 15, 2023

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Cameron Reynolds, certify that:

1. I have reviewed this annual report on Form 10-K of VolitionRx Limited;

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2023

By: */s/ Cameron Reynolds*
Cameron Reynolds
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Terig Hughes, certify that:

1. I have reviewed this annual report on Form 10-K of VolitionRx Limited;

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2023

By: */s/ Terig Hughes*
Terig Hughes
Chief Financial Officer and Treasurer

EXHIBIT 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certifications are hereby made in connection with the Annual Report on Form 10-K of VolitionRx Limited (the "Company") for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"):

I, Cameron Reynolds, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: March 15, 2023

By: */s/ Cameron Reynolds*
Cameron Reynolds
President and Chief Executive Officer

I, Terig Hughes, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: March 15, 2023

By: */s/ Terig Hughes*
Terig Hughes
Chief Financial Officer and Treasurer