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VolitionRx Ltd (NYSE: VNRX)

Heska Launches Nu.Q Vet Cancer Screening Test across the U.S.; Also, Second Global Supply Agreement Signed for the reference lab Nu.Q Vet Test; Clinical Studies in U.S. Planned on Nu.Q NETs.

A discounted cash flow (DCF) model that applies a 10% discount rate and a 2% terminal growth rate indicates a price target of $6.25 per share.

Current Price (11/02/22)	$1.93
Valuation	**$6.25**

OUTLOOK

Heska Launches **Nu.Q Vet Test in U.S.**; **European launch** to follow in the upcoming weeks.

Global Supply Agreement (through reference laboratory network) for **Nu.Q Vet Cancer Test** with a market leader in pet healthcare.

Clinical studies in the U.S. for Nu.Q NETs are planned through Diagnostic Oncology CRO and The University of Texas MD Anderson Cancer Center in order to pave the way for FDA approval.

Nu.Q NETs: An abstract was published and two posters presented in the past four months.

SUMMARY DATA

52-Week High	**$4.14**
52-Week Low	**$1.31**
One-Year Return (%)	**-46.03**
Beta	**1.82**
Average Daily Volume (shrs.)	**105,777**
Shares Outstanding (million)	**57.3**
Market Capitalization ($mil.)	**$110.6**
Short Interest Ratio (days)	**9.8**
Institutional Ownership (%)	**12.5**
Insider Ownership (%)	**12.3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/M**
P/E using 2022 Estimate	**N/M**
P/E using 2023 Estimate	**N/M**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Tech/Diagnostic**

ZACKS ESTIMATES

Revenue
(in thousands of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0.5 A	5.2 A	0.6 A	7.1 A	13.4 A
2021	25.5 A	24.8 A	25.5 A	14.2 A	90.9 A
2022	114 A	40 A	53 E	95 E	302 E
2023					500 E

Earnings per Share)
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.14 A	-$0.12 A	-$0.09 A	-$0.11 A	-$0.45 A
2021	-$0.12 A	-$0.10 A	-$0.13 A	-$0.15 A	-$0.51 A
2022	-$0.14 A	-$0.14 A	-$0.15 E	-$0.15 E	-$0.59 E
2023					-$0.61 E

Quarterly EPS may not equal annual EPS total due to rounding.

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RECENT EVENTS THUS FAR DURING 2H

Highlights

Volition, a multi-national epigenetics company, is focusing on developing diagnostic blood tests (assays) that can help detect a range of cancers and other diseases. The company's IP portfolio consists of over 90 granted patents and over 100 patents pending. Volition's most advanced product areas are **cancer screening tests for canines** and the **detection of NETosis**, an immune response related to an infection.

The company has begun to commercialize its **Nu.Q Vet** Cancer Test through **two supply agreements**:

a **point-of-care test with HESKA** and
through **reference laboratory network** with a market leader in pet healthcare

On November 3rd, **Heska launched the reference lab-version Nu.Q Vet Cancer Screening Test** across the U.S. with the European launch scheduled in a few weeks. The launch of the point-of-care version is scheduled for 2023. Moreover, Volition continues to advance the Nu.Q Vet assay through clinical papers, abstracts and posters, along with research and studies to expand the test to felines, equines and production animals.



VolitionRx Presentation October 2022

On the NETosis front, VolitionRx appointed **Diagnostic Oncology CRO**, LLC to develop and conduct large-scale clinical studies for Nu.Q NETs with the **objective** of **gaining approval from the FDA**. Volition also entered into a **Sponsored Research Agreement** with The University of Texas MD Anderson Cancer Center to **evaluate the role of NETs** in **cancer patients with sepsis**. A clinical study is to be entitled "*Correlation of Circulating NETs and Cell Free DNA with Inflammatory Immune Responses in Cancer Patients with Sepsis.*"

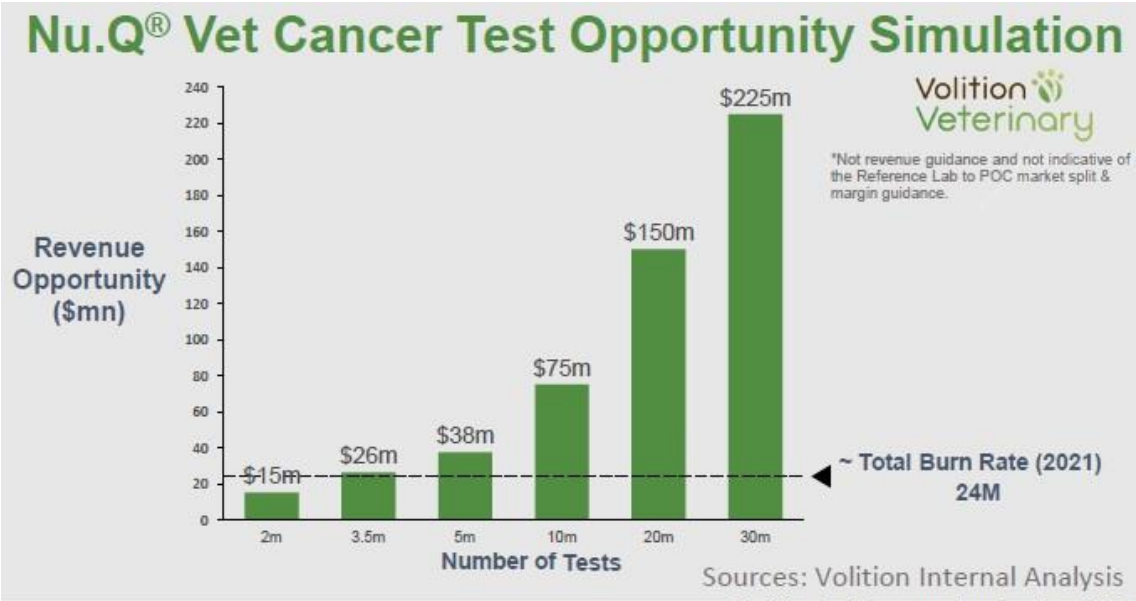
Commercialization of Nu.Q Vet Cancer Test

Heska has announced the **launch of the reference lab-version Nu.Q Vet Cancer Screening Test in the U.S.** The samples will be processed at Heska's Veterinary Diagnostic Laboratory. The product's launch in Europe is expected in a few weeks. This is a major milestone in the commercialization of the Nu.Q Vet test, which should accelerate the growth of the revenue stream

from this product. In addition, the launch will quicken the receipt of the $18 million in milestone payments that are part of the Supply Agreement with Heska.

In mid-October 2022**,** Volition signed a **Global Supply Agreement** for the Nu.Q Vet Cancer Test with a market leader in pet healthcare. Through the Agreement, Volition will provide its Nu.Q Vet Cancer Test and make its reference laboratory network available for the screening test of the blood samples drawn by veterinarians. Further details will be announced at the time of the official launch.

In its latest investor presentation, the company has shared its internal analysis of the **potential mass market** opportunity of the **Nu.Q Vet Cancer Test** (see image below).



VolitionRx Presentation October 2022

Nu.Q NETs

On August 8, 2022, VolitionRx appointed **Diagnostic Oncology CRO**, LLC (aka DXOCRO) to develop and conduct large-scale clinical validation studies for Volition's Nu.Q NETs and Nu.Q cancer tests in order to demonstrate significantly improved patient outcomes. Furthermore, DXOCRO will lead Volition's regulatory program in the U.S. with the goal of gaining clearance, authorization or approval from the FDA. Management anticipates pre-submission process with the FDA to begin in 2023. DXOCRO is a contract research organization that specializes in the commercialization of diagnostic biomarkers.

On August 10, 2022, VolitionRx announced that the company entered into a **Sponsored Research Agreement** with The University of Texas MD Anderson Cancer Center to **evaluate the role of NETs** in **cancer patients with sepsis**. A clinical study entitled "*Correlation of Circulating NETs and Cell Free DNA with Inflammatory Immune Responses in Cancer Patients with Sepsis*" will be conducted. The trial will investigate whether Volition's Nu.Q NETs test can **identify the development of sepsis in cancer patients earlier** so that treatments can be initiated sooner. Cancer patients have a weakened immune system and therefore, are more susceptible to developing sepsis by a factor of ten.

Financings During Third Quarter

In early August, an equity offering under the company's shelf registration statement provided **net proceeds of $6.4 million**, which is intended to fund research, continued product development, clinical studies, product commercialization and other general corporate purposes while in the short

bolstering working capital. The public offering consisted of **3,000,000 shares**, **plus an additional 450,000-share underwriter allotment**, priced at $2.00 per share. Newbridge Securities Corporation acted as the sole book-running manager.

Furthermore, VolitionRx was awarded an additional **$1.5 million of non-dilutive funding** from **Namur** Invest Capital Risk in Belgium. The award (which is structured as a 6% unsecured loan maturing July 31, 2026) will help fund the launch of **Nu.Q early access programs** at key sites across the EU, UK, and USA. Since 2016, VolitionRx has received over $14 million in non-dilutive funding from agencies within the Walloon Region.

Collaboration Agreements

In early August, VolitionRx and **Salarius Pharmaceuticals** (NASDAQ: SLRX) signed a **research and development collaboration** for the purpose of utilizing Volition's Nu.Q technology to epigenetically profile **seclidemstat**, Salarius' lead candidate in its product portfolio. Currently in Phase 1/2 clinical trials for relapsed/refractory Ewing's sarcoma, seclidemstat is a novel oral, reversible, targeted LSD1 inhibitor. The U.S. FDA has approved fast track, orphan drug and rare pediatric disease designations for seclidemstat as a therapy for Ewing's sarcoma. By supporting the development of seclidemstat, Volition's epigenetic assays should gain increased visibility for aiding development of drugs during the clinical trial process.

Also in early August, VolitionRx and **Xenetic Biosciences** (NASDAQ:XBIO) entered into a **research and development collaboration** to develop NETs targeted, adoptive cell therapies for the treatment of cancer. Xenetic recently in-licensed the DNase-Armored CAR T platform. Under the agreement, Volition will fund an early-stage exploratory research program focusing on **combining** Volition's **Nu.Q NETs** test **and** Xenetic's **DNase-Armored CAR T platform** in order to develop proprietary therapies for solid cancers. Volition's CE-marked Nu.Q NETs test detects nucleosomes which are present on and within cancerous solid tumors and the DNase-Armored CAR T platform is designed to enhance the function of CAR T cells, which are employed by immunotherapy techniques in treating certain cancers. Any proceeds from commercialization and/or licensing of products arising from the collaboration are to be shared by the two parties.

New Papers, Posters and/or Abstracts

On July 27, 2022, an abstract entitled "***NETosis and Nucleosome Biomarkers in Septic Shock and Critical COVID-19 Patients: An Observational Study***" was published on MDPI (fka Molecular Diversity Preservation International). The study concluded that "H3.1 and Cit-H3R8 nucleosomes appear to be interesting markers of global cell death and neutrophil activation when combined. Nu.H3.1 permits the evaluation of disease severity and differs between septic shock and critical COVID-19 patients, reflecting two distinct potential pathological processes in these conditions."

On October 13, 2022, two posters on **Nu.Q NETs** were presented at the 26th International Symposium on Infections in the Critically Ill Patient, namely ***Detection and evaluation of diseases associated with NETosis in Human Plasma using Nu.Q® NETs ChemiLuminescence Immunofluorescent Assay***" and "***Circulating nucleosomes are markers of NETosis and correlate with SOFA scores in sepsis***."

Second Quarter 2022 Financial Results

On August 10, 2022, VolitionRx reported financial results for the second quarter ending June 30, 2022. Total revenues were $39,752, which was composed of $29,706 from **product revenue from** sales of the **Nu.Q Vet cancer screening &** H3.1 kits and $10,046 from **services revenue from Nu.Q Discover**.

Operating expenses increased 37.4% from $5.93 million to $8.14 million. R&D, G&A and sales & marketing expenses for 2021 were restated as employee functionality was redefined. Never the less **the number of full-time employees (FTE) increased** from 42 to 57 in R&D, from 21 to 23 in G&A and from 5 to 19 in sales and marketing. Overall, higher personnel expenses, stock-based compensation and direct marketing & professional fees drove the increase in operating expenses.

For the second quarter, VolitionRx reported a net loss of $7.65 million (or $0.14 per diluted share) versus a net loss of approximately $5.23 million (or $0.10 per diluted share) in the comparable quarter last year.

As of June 30, 2022, working capital was approximately $1.3 million, declining from $8.4 million on March 31, 2022. Subsequently, in early August, working capital was bolstered by $6.4 million in net proceeds from an equity offering. Monthly cash burn was approximately $2.1 million during the quarter the second quarter. Shares outstanding increased by 0.1% to 53,846,973 shares from 53,772,261 shares on December 31, 2021.

Milestones Expected During 2022 - 2023

- **Nu.Q Vet Cancer**
  - Achievement of Heska Agreement milestones in order to receive $18 million in milestone payments
- **Silver One**: Under the **Nu.Q Discover** program, six contracts for processing samples utilizing Nu.Q Discovery assays were signed between late-2021 and the second quarter of 2022. These contracts have an aggregate annual worth of over $200,000 and are expected to ramp up in the second half. Additional contracts are anticipated, though due to the project-based nature of these contracts, Nu.Q revenues are expected to be lumpy.
- **Nu.Q NET**
  - In an effort to obtain FDA approval of **Nu.Q NETs**, , clinical studies are expected to begin through Diagnostic Oncology CRO, LLC and The University of Texas MD Anderson Cancer Center.
- Additional Papers, Posters and/or Abstracts
  - **Nu.Q Vet**
    - A **clinical study** with over 100 canines is in progress; the results are expected to be submitted in a peer-reviewed publication in 2022. Preliminary data suggests that Nu.Q Vet may be able to detect that a dog is coming out of remission weeks prior to the current methodology of physical detection.
    - The analysis of over 600 canines, 504 of which are cancer patients, has been accepted for publication by a veterinary journal and is currently under review.
  - **Large-scale Study of Lung Cancer** Conducted in Asia - The findings have been **submitted for presentation at two conferences** later in 2022.

HIGHLIGHTS – 1H 2022

Nu.Q NETs – CM Mark (Europe)

The **CE Mark** (Conformitè Europëenne) **certification process in Europe** for the company's Nu.Q NETs assay was **completed in late May 2022**. Volition registered the Nu.Q H3.1 NETs assay with a **broad claim** for detecting and monitoring diseases with a NETs component (e.g. sepsis, COVID-19, influenza, autoimmune diseases and cancer) and **across multiple platforms** (ELISA plate, automated beads etc.). The CE Mark enables the clinical use of the NETs assay test in more than 27 countries across Europe.

Data for published clinical studies have demonstrated that the level of circulating NETs **correlates with the current disease's severity** and also can be used to **predict future disease severity**, an important aspect in guiding treatment selection. With Neutrophil Extracellular Traps (NETs) having been discovered only in 2004, this nascent market has just begun to be fully understood and developed. Part of the body's response to infection (bacteria and viruses), certain white blood cells (neutrophils) produce and eject NETs to catch and kill the bacteria and viruses. The over-release of NETs is associated with poor patient outcomes in diseases, such as COVID-19 (excessive cytokine production that can result in acute respiratory distress) sepsis and cancer. The company's Nu.Q NETs assay enables medical professionals to monitor for elevated levels of NETs to help detect the immune system's status in terms of reaction and/or overreaction.

Recently, **Sharon Ballesteros** has joined Volition America as U.S Head of Quality and Development Process with the mandate to **navigate the Nu.Q NETs effort through the U.S. regulatory process** for the purpose of obtaining FDA approval. The plan to complete a U.S. clinical study includes an initial pilot study, which is expected to begin later in 2022.

Commercialization of Nu.Q Vet in Asia

The launch of the Nu.Q Vet test in Singapore through SAGE Healthcare (as an appointed distributor) occurred **in April 2022**. The target point of sale remains the routine wellness check-up for older dogs and at risk breeds so that the early detection of cancer can be affordably and effectively treated. In mid-December 2021, VolitionRx entered into non-exclusive License and Supply Agreement with SAGE Healthcare Private Limited for the Nu.Q Vet Cancer Screening Test in Asia.



Commercialization of Nu.Q Vet in U.S.

On March 29, 2022, VolitionRx announced the signing of an **exclusive Global License and Supply Agreement** with **Heska Corporation** (NASDAQ: HSKA) for the distribution of the Nu.Q Vet Cancer Screening Test **at the point-of-care** for companion animals. Heska is a growing veterinary health laboratory diagnostic systems company specializing in point-of-care tests, analyzers and specialty products for canines and felines in North America (62.6% of revenues) and 9 international markets.

VolitionRx received a $10 million upfront payment on March 30, 2022 and will receive up to an additional $18 million based upon the achievement of certain milestones with up to $13 million expected in the 2022-2023 timeframe and an additional $5 million milestone payment expected in 2024. Initially, the licensing agreement grants exclusive rights to commercialize Nu.Q Vet for canine cancer screening and monitoring at the point of care. Heska will offer the Nu.Q Vet test on its proprietary Element i+ Immunodiagnostic Analyzer point-of-care platform, which was launched in 2020. Element i+ is designed to deliver test results in minutes

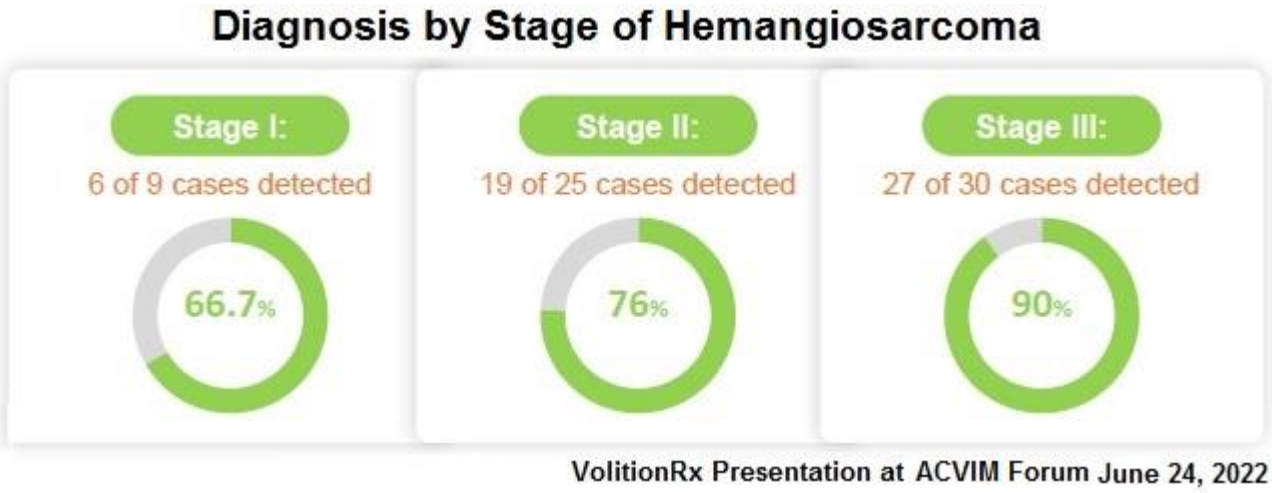
Also, Heska has been granted **non-exclusive rights to sell the Nu.Q Vet test kits through its reference laboratory network**. The payments for the kits and key components for both reference lab work and point-of-care services will be at pre-agreed prices, which should provide **another revenue stream** for VolitionRx.

VolitionRx estimates that the total addressable market (TAM) worldwide for cancer screening and monitoring in canines and felines to be about $11 billion. The managements of VolitionRx and Heska share the same vision of being able to provide **affordable diagnostic tests** that enable the early

detection and treatment of health conditions in order to achieve better outcomes. Nu.Q Vet tests are expected to be offered at a **price point of under $50** per kit (of which VolitionRx will receive around $10), which will position the test as **a mass market product** with the aim of supporting clinical decisions during annual check-ups, wellness exams and healthcare treatments. As a result, an **ongoing revenue stream** is expected to be generated by providing kits and key components to veterinarians around the world.

The **commercialization process** was anticipated to take at least six months as Nu.Q Vet test is adapted to Heska's Element i+ point-of-care platform, and potentially on Heska's multiplexed Heska panels. With the November 2022 launch of Heska's point-of-care Nu.Q Vet test in the U.S. **revenues should be generated in late 2022**.

On June 24, 2022, Volition presented at the American College of Veterinary Internal Medicine (ACVIM) Forum in Austin, Texas. The presentation is available on Volition's website at https://veterinary.volition.com/vet-resources/scientific-resources



Nu.Q NETs – Poster Presentation at ISTH

In mid-July 2022, a poster concerning NETosis and utilizing Volition's Nu.Q NETs Nu.H3.1 assay was published and presented at the International Society on Thrombosis and Haemostasis (ISTH). Entitled "**Evaluation and comparison of NETosis biomarkers in sepsis and COVID-19 patients**," the key finding from this study was the correlation reported between the Nu.Q NETs assay level and the currently used SOFA and APCHE-II score in sepsis patients. In addition, the Nu.Q NETs assay appears to be a marker of NETosis in COVID-19 patients.

Volition has sponsored an educational **GenomeWeb webinar** on NETs entitled "The Promise of Neutrophil Extracellular Traps (NETs) as Biomarkers in Inflammatory Disease." To view the webinar on demand, go to genomeweb.com.

Nu.Q Capture



Volition has sponsored an educational **GenomeWeb webinar** entitled "Novel Proteomics Approach to Epigenetic Profiling of Circulating Nucleosomes." To view the webinar on demand, go to genomeweb.com.

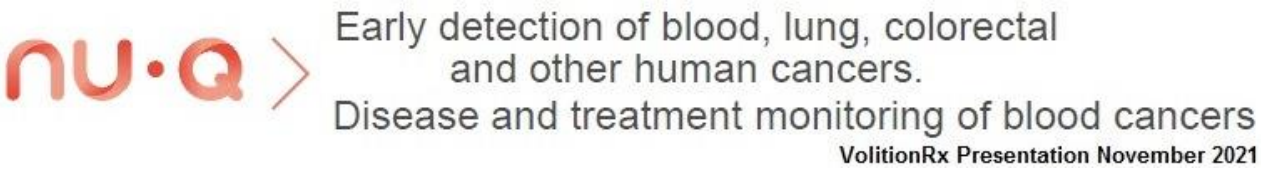
VolitionRx is now working on developing a large 1,000+ patient study in the areas of lung cancer and colorectal cancer. Further announcements about the study are expected later in 2022.

Nu.Q Discover (Silver One)

During 2021, a **Service Lab** was installed in **Silver One**. During the second quarter, Volition provided quotes to multiple pharmaceutical and biotechnology companies for processing samples under the **Nu.Q Discover** moniker. The **first Nu.Q Discover Agreement was signed in the fourth quarter of 2021**. An additional five contracts were signed in the first quarter of 2022. The **aggregate annual value of** these service contracts is **slightly over $200,000**. The customers include both pharmaceutical companies and academic research institutions which are using Volition's epigenetic platform to help profile disease models, preclinical testing and clinical trials.



Nu.Q Cancer – Updates on ongoing human studies in hematological, lung and colorectal cancers)



Updates on Large-Scale Blood, Lung and CRC Clinical Trials

*On-going Large-scale Study of **Colorectal Cancer** (CRC) Clinical Trial in Asia*

The **clinical data** of the **5,000-subject asymptomatic screening study** and the **2,000-subject symptomatic study**, along with the data logs, **were analyzed during the third quarter of 2021**. The initial findings were presented in **two posters** at the **2022 ASCO Gastrointestinal Cancers Symposium** in mid-February 2022.

*On-going Large-scale "Marquee" Study for **Lung Cancer** in Asia*

Volition has completed preliminary analysis of the lung cancer study and **abstracts have been submitted for presentations at two (2) lung cancer conferences** to be held later in 2022.

*On-going Clinical Trial for Diagnosis of **Non-Hodgkin's Lymphoma** (NHL) in the U.S.*

Due to delays caused by the COVID-19 pandemic, the study protocol of the 1,500-subject NHL study was altered in order to upgrade to a high-throughput platform, which should assist in the FDA approval process. Recruitment for the altered study is now expected to begin in the second quarter of 2022.

*On-going Large-scale "Marquee" Study for **Colorectal Cancer** (CRC) in the U.S.*

In June 2021, collections resumed for EDRN (Early Detection Research Network) study; enrollments have been slow, but steady. The EDRN continues to anticipate that the study will be completed in the fourth quarter of 2022.

OVERVIEW

VolitionRx is a multi-national **epigenetics company** with a focus on **developing diagnostic blood tests (assays)** that can help detect a range of cancers and other diseases so that appropriate treatment may be prescribed. Blood tests are a diagnostic tool that is relatively simple to administer, convenient and cost-effective. Also, as a front line screening modality, **blood tests would be the optimal approach for the diagnosis of life-threatening diseases** (especially cancer), where early diagnosis is the key factor for survivability.

Management's goal is to lead the foray and then dominate the epigenetics diagnostics space. The company has developed the **Nu.Q platform**, which is designed to accurately identify and measure the number of nucleosomes (and chromatin) in the bloodstream. Each Nu.Q blood assay or panel is intended to detect epigenetically-altered, circulating nucleosomes, which are biomarkers for cancer and other diseases. The company is in the process of developing and clinically testing multiple blood assays, particularly for lung, colorectal and hematological cancers.

Management's Conceptual Business Development Model

Management's **commercial strategy** involves targeting several specific markets.

- **Nu.Q Vet** – pursue full commercialization of the Nu.Q Vet blood assay in the United States, Asia and Europe
- **Nu.Q NETs** – research program to bring the Nu.Q H3.1 assay to commercialization for monitoring the progression of diseases associated with NETosis, such as sepsis, COVID-19 and influenza
- **Nu.Q Capture** – advance sample enrichment platform that enhances samples using mass-spectrometry and/or sequencing in order to be able to better identify new biomarker targets for the purpose of detecting tumors and other mutations
- **Nu.Q Cancer** – ongoing human studies in hematological, lung and colorectal cancers
- **Nu.Q Discover** – helps determine levels of circulating nucleosomes and provides epigenetic profiling in disease models, pre-clinical testing and clinical trials

Management is also looking to quickly advance its market opportunities by expanding and dominating each specific market by driving aggressive volume growth through attractive pricing.

VolitionRx has undertaken the task to address a global unmet need - the scarcity of robust, low-cost screens for cancer. For example, the predominant screens for **lung cancer** are a chest x-ray and/or CT scan, both of which subject patients to radiation. If a suspected area of cancer is detected, a biopsy follows, which has the associated risks of pneumonia, blood clots, infection, adverse anesthesia complications, pleural effusion or pneumothorax (i.e. a collapsed lung, which occurs in

15% of lung biopsy patients[i]). For **colorectal cancer**, a patient is advised to undergo a colonoscopy, which is invasive and can cause an infection, perforation (incidence of 1.96 per 1,000 procedures), bleeding and, in rare cases, death (probability of 0.01%[ii]). Therefore, many patients are reticent to undergo a colonoscopy, and some forgo the test altogether. For those who choose to avoid a colonoscopy and are later diagnosed with stage IV colorectal cancer, little more than 5% survive for five years. Conversely, those diagnosed with stage I bowel cancer (through early detection) have a five-year survival rate of 89.8%.[iii] An early diagnosis of both lung and colorectal cancer dramatically improves a patient's outcome. A low-risk, low-cost, blood-based test would aid in realizing an earlier diagnosis for many patients.

R&D Center (Isnes, Belgium)



VolitionRx Presentation May 13, 2020

The company's **principal research and development center** is located in Isnes, **Belgium**. Opened in 2017, the **custom-designed facility** has 20,000 sq. ft. of office and R&D space, of which 10,000 square feet is devoted to the laboratory. Here, the company has the ability to conduct R&D and clinical studies in-house.

Production Facility - Silver One (Namur, Belgium)

In 2020, VolitionRx acquired a **10,000 square-foot building** (dubbed **Silver One**), which is located in Namur, Belgium in close proximity to the company's R&D center in Isnes. After refurbishing and equipping the building, the manufacturing facility opened on January 25, 2021 and by May 2021 began producing recombinant nucleosomes for in-house use for the company's Nu. Q assay product line. The new facility not only brings the manufacture of components in-house, but also will significantly reduce production costs of the company's assay products.

The building will serve as a production facility for components and supply kits, a contract research facility and a service laboratory, which can provide sample processing services for third parties. In addition, management is pursuing opportunities to provide **laboratory services** or to act as a **contract research facility** (branded as **Nu.Q Discover**) for external parties, such as pharmaceutical companies, bio-tech companies and academic researchers.

VNRX Added to the Russell 3000 and Russell Microcap Indexes

VolitionRx was added to both the **Russell 3000** and **Russell Microcap Indexes** effective on the close of June 26, 2020. The Russell indexes are reconstituted annually and many mutual funds benchmark to these indices. Consequently, the **shareholder base** of VolitionRx ought to **broaden**, and the stock should experience **greater liquidity**. In addition, the inclusion of the company's stock into these two Russell indices should **expand awareness** of VolitionRx among investors, both retail and institutional.

LARGE-SCALE BLOOD, LUNG and CRC CLINICAL TRIALS

*On-going Large-scale "Marquee" Study for **Lung Cancer** in Asia*

In May 2019, VolitionRx signed a formal contract with the **National University of Taiwan to conduct a large-scale lung cancer study**. The study includes **1,200 participants** receiving Low-Dose CT (LDCT) scan, 1,000 of which have lung cancer. Collection commenced in the summer of 2019, but the COVID-19 pandemic impacted the sample gathering process. In **May 2021, the target number of patient cohorts had been collected**. The Nu.Q H3.1 assays were processed, and Volition completed the preliminary analysis of the lung cancer study.

An **abstract** on Nu.Q performance in **lung cancer detection was presented** at the **IASLC World Conference on Lung Cancer** (WCLC) conference **in January 2021**. The presentation, which was based on an **interim analysis of a subset of 220 subjects**, indicated that the Nu.Q H3.1 assay could help identify non-cancerous nodules following a LDCT scan. As a result, up to 32% of the subjects that were LDCT positive could avoid unnecessary follow-up biopsies.

This large lung cancer study has been completed and that the **findings have been submitted to two conferences** to be held in 2022. Management plans to initiate an FDA 510(k) regulatory study in the U.S. for lung cancer.

*On-going Large-scale Study of **Colorectal Cancer** (CRC) Clinical Trial in Asia*

In July 2018, VolitionRx signed an agreement with the **National University of Taiwan to conduct two, large-scale, three-year colorectal cancer studies**: a 5,000 subject asymptomatic screening study and a 2,000 subject symptomatic study. The COVID-19 pandemic impacted the sample gathering process; nevertheless, the collections were completed in mid-2021. The **clinical data**, along with the data logs, **was analyzed during the third quarter of 2021**. The findings were **presented** as posters at **ASCO Gastrointestinal Cancers Symposium in February 2022**.

*On-going Clinical Trial for Diagnosis of **Non-Hodgkin's Lymphoma** (NHL) in the U.S.*

In November 2020, Volition engaged Diagnostic Oncology CRO LLC (a contract research organization) to conduct a program that will lead to multiple FDA 510(k) submissions for Nu.Q assay(s) that will assist physicians in distinguishing five of the most common forms of **Non-Hodgkin's Lymphoma** (NHL) from common conditions. At a cost of approximately $2.9 million, the effort includes a **1,500-subject clinical trial** and data analysis, along with the preparation of regulatory and reimbursement submissions. The trial is planned to be conducted across 10 major U.S. healthcare institutions.

After initial delays caused by the COVID-19 pandemic, the study protocol was altered in order to upgrade to a high-throughput platform, which should assist in the FDA approval process. Now, management anticipates that recruitment for the altered study will begin in the second quarter of 2022.

On-going Large-scale "Marquee" Study for Colorectal Cancer (CRC) in the U.S.

After a pause on collecting samples for the U.S. EDRN study for colorectal cancer (6,000 subjects) that began in May 2020 due the COVID-19 pandemic, enrollments were re-initiated in June 2021. Enrollments have been slow, but steady, and management anticipates that the study will be completed in the fourth quarter of 2022.

Colorectal Cancer Testing Product - China

As part of Volition's project with Shanghai Fosun Long March Medical Science Co., Ltd to adapt and transfer VolitionRx's assays for use on Fosun's open-access LUMIART-II Automated Chemiluminescence Immunoassay platform, **Volition has been in continuing negotiations with Fosun for a licensing agreement**, which could lead to a launch a human colorectal cancer testing product in China.

LUNG CANCER

In early 2019, VolitionRx conducted a lung cancer **proof-of-concept study** with **76 subjects**. A Nu.Q assay detected lung cancer, including stage I cancer, with an **AUC of 85%** (cancer versus healthy). In a second confirmatory cohort with **152 subjects**, the same, single Nu.Q assay detected lung cancer with an **AUC of 79%**.

In May 2019, VolitionRx signed a formal contract with the **National University of Taiwan to conduct a large-scale lung cancer study**. The study includes **1,200 participants** receiving low-dose CT scan, 1,000 of which have lung cancer. Collection commenced in the summer of 2019, but the COVID-19 pandemic impacted the sample gathering process.

On January 28, 2021, VolitionRx had an **abstract presented** at the IASIC World Conference on Lung Cancer on a **220-subject subset** of the on-going 1,200-subject, **large-scale lung cancer study**. The abstract entitled *Circulating Nucleosomes in Lung Cancer Diagnosis following Low-Dose Computed Tomography* was virtually presented by Dr. Tung-Ming Tsai of the **National Taiwan University Hospital**.

The data suggests that Nu.Q™ assays could help identify non-cancerous nodules following a Low-Dose Computed tomography (LDCT) scan. LDCTs have limitations including poor specificity (i.e. a high percentage of false positives). The study's results suggest that Nu.Q assay for nucleosome detection may be able to discriminate well between non-cancerous benign nodules versus early-stage lung cancer. This ability **could reduce the number of unnecessary biopsies by as much as 32%**.

The study is beginning to provide the first statistically-powered evidence of the potential utility of Nu.Q diagnostics as a screen for lung cancer or as an adjunct/triage test for low-dose CT. LDCT, currently the only recommended screening test for lung cancer, has drawbacks including its relatively high cost, patient exposure to radiation, over-diagnosis and a potential for meaningful rates of false-positives. As such, an adjunct or triage test that could improve accuracy of lung cancer screening and/or reduce the need for LDCT (without compromise to diagnosis) could have massive appeal, in our opinion.

A review of the data with Professor Chen of the National University of Taiwan and his team continues to be planned. This large lung cancer study has been completed and that the **findings have been submitted to two conferences to be held in 2022**. If the study's data continues to be positive, management plans to initiate an FDA 510(k) regulatory study in the U.S. for lung cancer.

COLORECTAL CANCER (CRC)

In early 2019, VolitionRx conducted a CRC **proof-of-concept study** with **123 subjects**, a single Nu.Q assay detected CRC with an **AUC of 72%** (cancer versus healthy). In the same cohort, a two-assay panel, which included the initial Nu.Q assay and an inflammatory biomarker test, had an **AUC**

of 84%. The goal will be to replicate and confirm these results with reproducible assays in a larger study.

VolitionRx has **three large-scale, ongoing colorectal cancer studies**, two being conducted in Asia at the National University of Taiwan and the third in the United States at the Early Detection Research Network of the U.S. National Cancer Institute

In July 2018, VolitionRx signed an agreement with the **National University of Taiwan to conduct two, large-scale, three-year colorectal cancer studies**: a 5,000 subject asymptomatic screening study and a 2,000 subject symptomatic study. The COVID-19 pandemic impacted the sample gathering process; nevertheless, the collections were completed in mid-2021. The **clinical data**, along with the data logs, **was analyzed during the third quarter of 2021**. The findings were **presented** as posters at **ASCO Gastrointestinal Cancers Symposium in February 2022**.

In the U.S., Volition has an on-going large-scale "Marquee" Study for Colorectal Cancer (CRC) being conducted at the EDRN of the U.S. National Cancer Institute. The target number of samples for the prospective sampling in the EDRN trial (in the table below) is now at a minimum of 6,000 subjects.

After a pause on collecting samples for the U.S. EDRN study for colorectal cancer (6,000 subjects) that began in May 2020 due the COVID-19 pandemic, enrollments were re-initiated in June 2021. Enrollments have been slow, but steady, and management anticipates that the study will be completed in the fourth quarter of 2022.

VolitionRx's CRC Clinical Trials

Institution	Condition	Sample Collection	Cohort
Early Detection Research Network of the U.S. National Cancer Institute (EDRN)	Colorectal Cancer	9,000 Prospective, 4,600 Retrospective	13,500 + Screening Population
National Taiwan University	Colorectal Cancer	Prospective	5,000 Asymptomatic Patients
National Taiwan University	Colorectal Cancer	Prospective	2,000 Symptomatic Patients

VolitionRx 10-K 2018

HEMATOPOIETIC (BLOOD-BORNE) CANCER

In December 2019, VolitionRx announced the results from **a proof of concept study** with 54 subjects diagnosed with hematopoietic cancers. A single Nu.Q assay was used to investigate whether the hematopoietic cancer could be detected. The Nu.Q assay detected blood cancer with an AUC of 91% (cancer vs. healthy). Specifically, the test detected 80% of the subjects diagnosed with Non-Hodgkin's Lymphoma, Acute Lymphocytic Leukemia and Acute Myeloid Leukemia at 95% specificity among healthy subjects. A number of other assays in development also demonstrated promising individual assay results with AUCs ranging from 79% to 91%.

The Nu.Q assay appears quite robust and seems to have high sensitivity. The results of this proof of concept study suggest that the Nu.Q assay could be potentially used to screen people for early detection of a wide variety of cancers.

Nu.Q™ CAPTURE TECHNOLOGY

Nu.Q Capture technology is based on the ability to **extract and isolate nucleosomes** (chromosome fragments) from blood samples. Consequently, the technology is able to isolate the

nucleosomes containing particular epigenetic signals from the other particles in the blood that cause background noise, which **should improve accuracy** by reducing the number of false positives and false negatives. The isolation of nucleosomes would also allow for further investigation of those nucleosomes with mass spectrometry for further analysis and identification, which **could lead to the discovery of other biomarkers**. After Nu.Q Capture technology has been sufficiently advanced, **management plans to integrate Nu.Q Capture with Nu.Q assays**. Also, there could be a licensing opportunity to enable other companies in the liquid biopsy space to produce enriched samples (utilizing the Nu.Q Capture process) that would enhance their efforts in sequencing research.

Chromosomes from healthy cells are different from cancer cells both in their genetic sequence and in terms of their protein structure due to epigenetic differences. When cells die (apoptosis), chromosomes are degraded by enzymes, and the resulting fragmentation releases subunits called nucleosomes. These now circulating nucleosomes retain the epigenetic information of the chromosome. Nucleosomes from healthy chromosomes are slightly longer than those from cancerous chromosomes due to the linking characteristics of healthy DNA.

Nu.Q Capture is designed to pull out healthy nucleosomes from a plasma sample. Magnetic beads (that are coated with a protein that binds to linker DNA) are inserted into the plasma sample. Only the nucleosomes with linker DNA (healthy chromosomes) bind to the magnetic beads. The sample is then subjected to a magnetic field, drawing aside the magnetic beads with the longer healthy nucleosomes attached, allowing for the extraction of the shorter nucleosomes. The process allows for the capture and separation of shorter (potentially malignant) nucleosomes from a plasma sample. Analysis of the enriched sample of shorter nucleosomes (and their associated DNA content) is more accurate for diagnostic applications and disease monitoring due to the removal of the background noise from healthy, longer chromosomes. Also, it is easier to identify new biomarker targets in enriched samples through mass spectrometry.

In late May 2020, VolitionRx shared data at the ASCO meeting from a study on colorectal cancer that used the new enhanced Nu.Q Capture process. The study clearly demonstrated the separation of short and long nucleosomes from cancer cell lines and no difference in samples from healthy controls.

On May 4, 2021, a clinical paper entitled *Serial profiling of cell-free DNA and nucleosome histone modifications in cell cultures* was published in Nature's Scientific Reports. This first paper on Nu.Q Capture detailed the company's novel approach to epigenetic profiling of select circulating nucleosomes in the blood of cancer patients in order to identify new biomarkers.

The first two clinical papers concerning **Nu.Q Capture** (*A Novel Proteomics Approach to Epigenetic Profiling of Circulating Nucleosomes* and *Serial profiling of cell-free DNA and nucleosome histone modifications in cell cultures*) were published in the first half of 2021. The second half **saw the continued recruitment of team members** for Nu.Q Capture research at the innovation hub in San Diego. Multiple methods for enrichment have been identified, along with using Nu.Q Capture in combination with sequencing, other Nu.Q assays and mass spectrometry. Also, Nu.Q Capture technology was used in the poster (concerning canines with lymphoma) that was presented at the VCS Society Annual Conference.

VALUATION

Utilizing a financial model based on DCF methodology, which forecasts out to 2029, and uses a 10% discount rate (based on CAPM) and a 2% terminal growth rate, the indicated value of VNRX is **$6.25 per share**.

RISKS

- VolitionRx is a clinical stage company. Since its formation, the company has incurred losses due to the continued spending on the time-consuming and costly efforts to discover and develop diagnostic products, including conducting clinical studies, obtaining regulatory clearance/approval in the United States, Asia and Europe Management expects continued losses from ongoing research and development expenses, along with administrative, manufacturing, sales and marketing expenses.

- Additional capital is required to continue funding management's strategic plan of commercializing the Nu.Q platform through the development of a suite of blood-based diagnostic tests. To date, VolitionRx has been successful in raising capital to fund the company's initiatives.

- As part of the effort to raise capital, shares outstanding have increased steadily over the last few years. Shares outstanding increased 33.2% in 2018, 16.4% in 2019, 18.2% in 2020 and +10.6% in 2021 as equity financings have helped fund the company's research & development costs and general corporate expenses. Through June 30, 2022, shares outstanding increased only 0.1%, but subsequent equity financings during the third quarter have resulted in a 6.6% increase in 2022. Commercialization of the company's products is expected to mitigate the rate of shareholder dilution.

- If third parties are believed to have infringed on the company's patents, the ensuing litigation would be time-consuming and costly. Conversely, third parties might believe that their proprietary rights have been infringed, which might also result in time-consuming and costly litigation, along with potentially impinging on VolitionRx's ability to manufacture and sell certain future products

BALANCE SHEET

VolitionRx Limited					
(in $US except share data)	2018	2019	2020	2021	2Q 2022
Period ending	12/31/2018	12/31/2019	12/31/2020	12/31/2021	6/30/2022
ASSETS					
Cash and cash equivalents	13,427,222	16,966,168	19,444,737	20,581,313	16,730,441
Accounts receivable	-	-	7,118	12,510	8,489
Prepaid expenses	245,441	267,518	303,178	598,367	936,068
Other current assets	229,755	322,593	576,660	786,642	973,979
Total Current Assets	**13,902,418**	**17,556,279**	**20,331,693**	**21,978,832**	**18,648,977**
Property, plant and equipment	3,119,643	2,981,225	5,171,134	4,911,077	4,807,729
Operating lease right-of-use assets	-	381,483	326,085	383,551	739,015
Intangible assets	466,905	372,305	321,641	216,876	151,314
TOTAL ASSETS	**17,488,966**	**21,291,292**	**26,150,553**	**27,490,336**	**24,347,035**
Accounts payable	807,162	627,253	1,539,547	1,542,457	2,602,351
Accrued liabilities	923,034	2,168,588	3,491,740	3,841,013	3,236,981
Deferred revenue					10,000,000
Management and directors' fees payable	1,200	21,979	55,174	71,303	74,261
Current portion of long-term debt	416,553	647,569	841,319	797,855	1,085,089
Current portion of financing lease liabilities	145,150	97,946	59,930	48,958	44,293
Current portion of operating lease liabilities	-	257,244	179,624	171,166	241,838
Deferred grant income	-	-	-	-	-
Current portion of grant repayable	40,094	39,295	69,218	43,100	65,814
Total Current Liabilities	**2,333,193**	**3,859,874**	**6,236,552**	**6,515,852**	**17,350,627**
Long-term debt	1,984,262	2,195,278	2,606,885	2,270,767	1,743,156
Financing lease liabilities	720,013	607,708	601,967	511,086	447,880
Operating lease liabilities	-	131,875	151,828	217,305	519,485
Grant repayable	311,042	297,991	259,603	253,221	206,785
Non-Current Liabilities	**3,015,317**	**3,232,852**	**3,620,283**	**3,252,379**	**2,917,306**
TOTAL LIABILITIES	**5,348,510**	**7,092,726**	**9,856,835**	**9,768,231**	**20,267,933**
SHAREHOLDERS' EQUITY					
Common Stock	35,335	41,125	48,607	53,772	53,847
Additional paid-in capital	85,604,271	103,853,627	126,526,239	154,730,938	156,441,677
Accumulated other comprehensive income	223,651	125,670	(59,978)	148,326	244,519
Accumulated deficit	(73,722,801)	(89,821,856)	(110,173,971)	(136,988,636)	(152,272,367)
Total VolitionRx Stockholders' Equity	**12,140,456**	**14,198,566**	**16,340,897**	**17,944,400**	**4,467,676**
Non-controlling interest	-	-	(47,179)	(222,295)	(388,574)
Total Stockholders' Equity	**12,140,456**	**14,198,566**	**16,293,718**	**17,722,105**	**4,079,102**
TOTAL LIABILITIES & STOCKHOLDERS' EQUIT	**17,488,966**	**21,291,292**	**26,150,553**	**27,490,336**	**24,347,035**
Shares outstanding	35,335,378	41,125,303	48,607,017	53,772,261	53,846,973

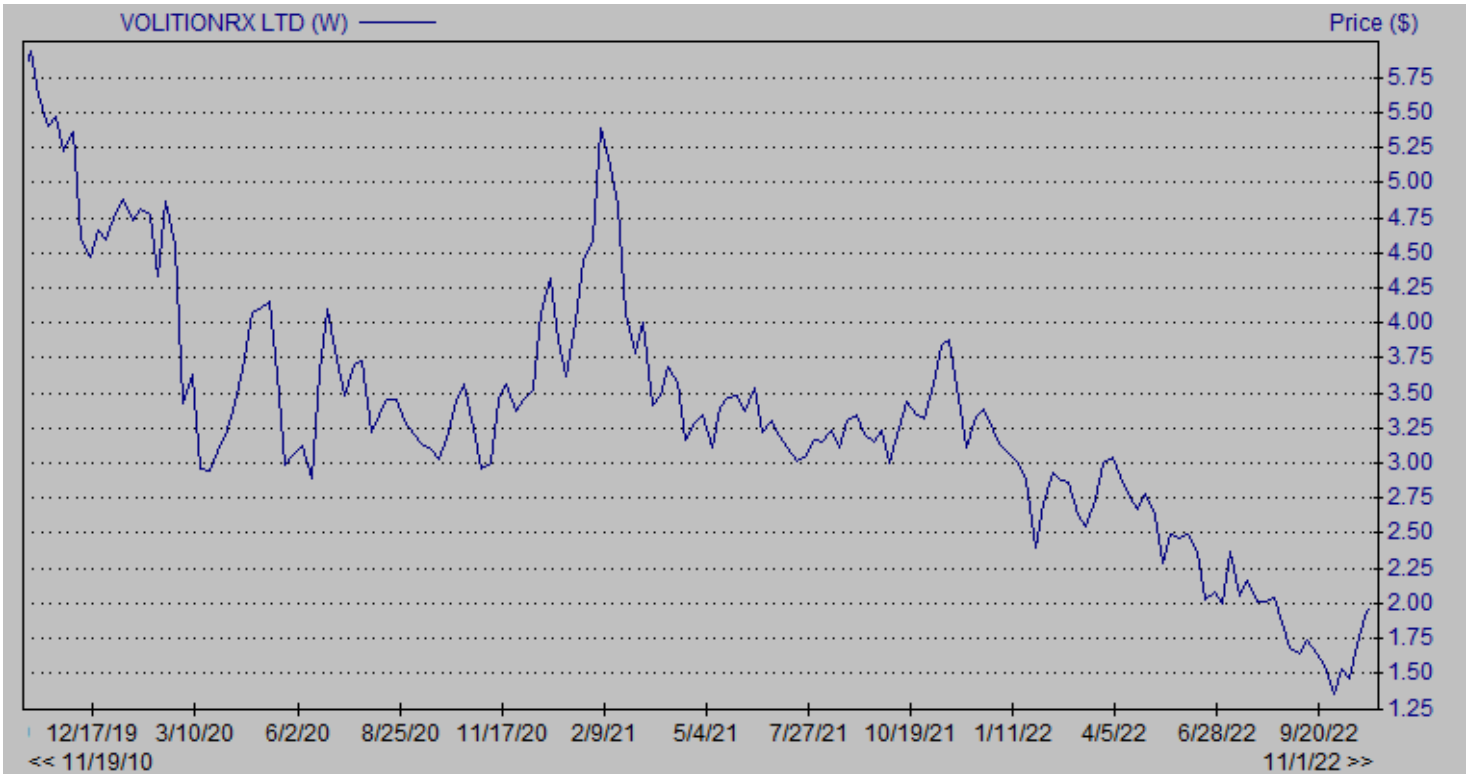
PROJECTED ANNUAL INCOME STATEMENTS

VolitionRx Limited					
Income Statement	2018	2019	2020	2021	2022 Est.
(in $US, except share and per share data)	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
Product	-	-	11,321	90,035	186,340
Agreement Fee					0
Service (Contract lab services)	-	16,204	0	0	115,300
Royalty (Research kits)	-	892	2,112	0	0
Total Revenues	**0**	**17,096**	**13,433**	**90,035**	**301,640**
Expenses					
Research and development	10,906,871	10,363,253	14,533,862	15,541,889	13,726,112
General and administrative	5,821,072	4,731,054	5,654,018	8,751,392	12,140,175
Sales and marketing	1,169,756	965,713	1,073,368	4,129,833	7,358,304
Total Operating Expenses	**17,897,699**	**16,060,020**	**21,261,248**	**28,423,114**	**33,224,592**
Loss Before Other Income	**(17,897,699)**	**(16,042,924)**	**(21,247,815)**	**(28,333,079)**	**(32,922,952)**
Grant income	-	155,031	635,513	1,522,533	393,440
Interest income	-	112,367	49,495	2,734	12,263
Interest (expense)	(110,924)	(126,572)	(129,799)	(155,803)	(155,794)
Gain on disposal of fixed assets	-	-	293,312	(26,166)	0
Other income (expense)	-	(196,957)	0	0	0
Total Other Income (Expenses)	**(110,924)**	**(56,131)**	**848,521**	**1,343,298**	**249,909**
Net Gain (Loss)	**(18,008,623)**	**(16,099,055)**	**(20,399,294)**	**(26,989,781)**	**(32,673,043)**
Net Gain (Loss) Non-Controlling Int.	-	-	(47,179)	(175,116)	(278,026)
Net Gain (Loss) - VNRX Stockholders	**(18,008,623)**	**(16,099,055)**	**(20,352,115)**	**(26,814,665)**	**(32,395,017)**
Basic and diluted loss per share	**(0.57)**	**(0.41)**	**(0.45)**	**(0.51)**	**(0.59)**
Wgted. Avg. Shares Out. - diluted	31,389,220	39,180,369	45,278,847	52,655,885	55,248,555

QUARTERLY INCOME STATEMENTS

VolitionRx Limited						
Income Statement (in $US except share and per share data)	**2021 12/31/2020**	**1Q 2022 3/31/2021**	**2Q 2022 6/30/2021**	**3Q E 2022 9/30/2021**	**4Q E 2022 12/31/2021**	**Estimate 2022 12/31/2021**
Product	90,035	53,957	29,706	32,677	70,000	186,340
Agreement Fee	-	0	0	0	0	0
Service (Contract lab services)	0	60,254	10,046	20,000	25,000	115,300
Royalty (Research kits)	0	0	0	0	0	0
Total Revenues	**90,035**	**114,211**	**39,752**	**52,677**	**95,000**	**301,640**
Expenses						
Research and development	15,541,889	3,590,053	3,279,323	3,377,703	3,479,034	13,726,112
General and administrative	8,751,392	2,602,152	3,085,840	3,178,415	3,273,768	12,140,175
Sales and marketing	4,129,833	1,598,983	1,774,064	1,915,989	2,069,268	7,358,304
Total Operating Expenses	**28,423,114**	**7,791,188**	**8,139,227**	**8,472,107**	**8,822,070**	**33,224,592**
Loss Before Other Income	**(28,333,079)**	**(7,676,977)**	**(8,099,475)**	**(8,419,430)**	**(8,727,070)**	**(32,922,952)**
Grant income	1,522,533	0	393,440	0		393,440
Interest income	2,734	2	11,161	700	400	12,263
Interest (expense)	(155,803)	(41,032)	(37,129)	(38,243)	(39,390)	(155,794)
Gain (loss) disposal of fixed assets	(26,166)	0	0	0	0	0
Other income (expense)	0	0	0	0	0	0
Total Other Income (Expenses)	**1,343,298**	**(41,030)**	**367,472**	**(37,543)**	**(38,990)**	**249,909**
Net Gain (Loss)	**(26,989,781)**	**(7,718,007)**	**(7,732,003)**	**(8,456,973)**	**(8,766,060)**	**(32,673,043)**
Net Gain (Loss) Non-Controlling Int.	(175,116)	(83,977)	(82,302)	(54,871)	(56,876)	(278,026)
Net Gain (Loss) - VNRX Stockholders	**(26,814,665)**	**(7,634,030)**	**(7,649,701)**	**(8,402,102)**	**(8,709,184)**	**(32,395,017)**
Basic and diluted loss per share	**(0.51)**	**(0.14)**	**(0.14)**	**(0.15)**	**(0.15)**	**(0.59)**
Wgted. Avg. Shares Out. - diluted	52,655,885	53,775,096	53,810,500	56,111,650	57,296,973	55,248,555

HISTORICAL STOCK PRICE



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