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Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

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VolitionRx Ltd (NYSE: VNRX)

Nu.Q NETs receives **CE mark** with a broad claim for detecting & monitoring diseases with a NETs component. **Nu.Q Vet test** launched in **Singapore** through SAGE Healthcare. **Nu.Q Discover** - **six contracts** signed.

A discounted cash flow (DCF) model that applies a 10% discount rate and a 2% terminal growth rate indicates a price target of $7.83 per share.

Current Price (07/22/22)	$2.17
Valuation	**$7.83**

OUTLOOK

Nu.Q NETs receives **CE mark** in Europe with a broad claim for detecting & monitoring diseases with a NETs component.

Nu.Q Vet test launched **in Singapore** through **SAGE Healthcare.**

Nu.Q Discover - six contracts signed.

Multiple **presentations at conferences** on **Nu.Q Vet test** and **Nu.Q NETs**.

SUMMARY DATA

52-Week High	**$4.14**
52-Week Low	**$1.95**
One-Year Return (%)	**-29.08**
Beta	**1.70**
Average Daily Volume (shrs.)	**46,171**
Shares Outstanding (million)	**53.85**
Market Capitalization ($mil.)	**$116.8**
Short Interest Ratio (days)	**15.7**
Institutional Ownership (%)	**11.4**
Insider Ownership (%)	**8.3**
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 $US)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	0.0 A	0.0 A	17.1 A	0.0 A	17.1 A
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	124 E	140 E	152 E	531 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.12 A	-$0.11 A	-$0.10 A	-$0.09 A	-$0.41 A
2020	-$0.14 A	-$0.12 A	-$0.09 A	-$0.10 A	-$0.45 A
2021	-$0.12 A	-$0.10 A	-$0.13 A	-$0.15 A	-$0.51 A
2022	-$0.14 A	-$0.15 E	-$0.14 E	-$0.14 E	-$0.57 E

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

TIMELINE OF RECENT EVENTS

In April 2022, the **Nu.Q Vet test** was **launched in Singapore** through **SAGE Healthcare**, which expanded the Nu.Q Vet test's geographic footprint to Asia.

In late May 2022**, Nu.Q NETs assay** completed the European **CE Mark** (Conformitè Europëenne) certification process for detecting and monitoring diseases with a NETs component.

On May 26, 2022, Dr. Wilson-Robles advanced **Nu.Q Vet** by presenting "Monitoring treatment response and disease progression in canine lymphoma using serial plasma nucleosome concentrations" at the European **Society of Veterinary Oncology** (ESVONC).

On June 24, 2022, Dr. Heather Wilson-Robles presented "Evaluation of Plasma Nucleosome Concentrations in Healthy Dogs and Dogs with Various Common Cancers" at **the American College of Veterinary Internal Medicine** (ACVIM) **Forum** in Austin, Texas. A slide deck of the presentation is available on Volition's website at https://veterinary.volition.com/vet-resources/scientific-resources.

In mid-July 2022, **a poster** concerning NETosis and utilizing Volition's **Nu.Q NETs assay** ("Evaluation and comparison of NETosis biomarkers in sepsis and COVID-19 patients") was presented at the **International Society on Thrombosis and Haemostasis** (ISTH).

VolitionRx announced that it is **developing a 1000+s patient Nu.Q Capture study** in lung cancer and colorectal cancer. Further announcements are expected later in 2022.

Volition 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.

Volition has a **webinar** available on its **Nu.Q Vet cancer diagnostic test**, including case studies and how veterinarians should interpret test results. To view on demand, go to https://us02web.zoom.us/webinar/register/WN_dxFl_IpCRHWXpZSCuVawOg

OPERATIONAL 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 are 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.

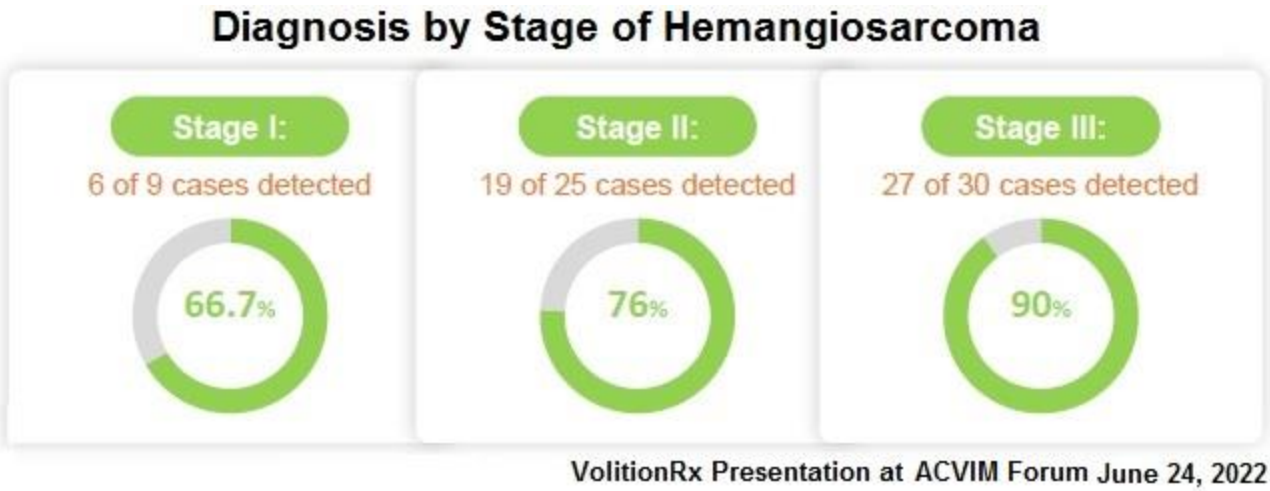
VolitionRx received a $10 million upfront payment on March 30, 2022 and will receive up to an additional $18 million based upon the achievement of certain milestones with up to $13 million expected in the 2022-2023 timeframe and an additional $5 million milestone payment expected in 2024. Initially, 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** is 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. **Revenues could be generated as early as 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

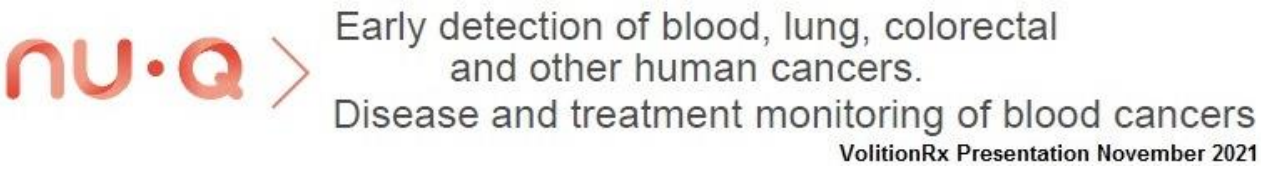
Volition has sponsored an educational **GenomeWeb webinar** entitled "Novel Proteomics Approach to Epigenetic Profiling of Circulating Nucleosomes." To view the webinar on demand, go to genomeweb.com.

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.

Milestones Expected During 2022 - 2023

- **Nu.Q Vet Cancer**
  - Achievement of Heska Agreement milestones in order to receive $18 million in milestone payments
  - Additional announcements of licensing agreement(s) for the distribution of **Nu.Q Vet Cancer Screening Test** nationally and/or internationally. VolitionRx continues to be in negotiations with other companies.
- **Silver One**: Under the **Nu.Q Discover** program, six contracts for processing samples utilizing Nu.Q Discovery assays were signed in late-2021 and the first quarter of 2022. These contracts have an aggregate annual worth of slightly over $200,000, but are expected to ramp up slowly throughout 2022, but particularly in the second half.
- **Nu.Q NET**
  - In an effort to obtain FDA approval of **Nu.Q NETs**, a pilot study is expected to begin later in 2022.
- Additional Papers, Posters and/or Abstracts
  - **Nu.Q Vet**
    - The results of a **clinical study** with over 100 canines is in progress with the results are expected to be submitted in a peer-reviewed publication in 2022. Preliminary data suggest 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.

RECENT FINANCIAL REPORTS

First Quarter 2022 Financial Results

On May 11, 2022, VolitionRx reported financial results for the first quarter ending March 31, 2022. Total revenues were $144,211, which was driven by **services revenue from Nu.Q Discover** and **product revenue from** sales of the **Nu.Q Vet cancer screening** and H3.1 kits.

Operating expenses increased 27.5% from $6.11 million to $7.79 million. R&D expenses declined 7.3% to approximately $3.59 million. G&A expenses increased 43.8% to approximately $2.60 million, as the number of full-time employees (FTE) increased from 14 to 19. Sales and marketing expenses increased 274% due to higher personnel expenses, stock-based compensation and direct marketing & professional fees as FTE personnel increased by seven to 18.

For the first quarter, VolitionRx reported a net loss of $7.63 million (or $0.14 per diluted share) versus a net loss of approximately $6.12 million (or $0.12 per diluted share) in the comparable quarter last year.

As of March 31, 2022, working capital was approximately $844 million, declining from $15.5 million on December 31, 2021. Shares outstanding increased by 1.1% to 53,790,261 shares from 53,223,761 shares on December 31, 2021.

OVERVIEW

VolitionRx is a multi-national **epigenetics company** with a focus on **developing 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 amount 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** has been fine-tuned into **four pillars** composed of Nu.Q Vet, Nu.Q NETs, Nu.Q Capture and Nu.Q.

- **Nu.Q Vet** – pursue full commercialization of the current beta-launched 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 a 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 a 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.

RECENT FINANCINGS

In early January 2021, VolitionRx was awarded a **cash grant of $1.3 million** and **$2.7 million in loans** from the Walloon Region and Namur Invest, Belgium. This non-dilutive funding brings the total amount awarded from agencies from the Walloon Region to approximately $13 million.

On February 12, 2021, VolitionRx closed a public offering of 3,809,524 shares priced at $5.25 per share. **Net proceeds** are estimated to be approximately **$18.87 million**, which will be used for continued product development, clinical studies, product commercialization, working capital and general corporate purposes, including potential strategic acquisitions. The offering was pursuant to a shelf registration statement, and Cantor Fitzgerald & Co. was the sole book running manager.

During 2021, Volition received **net proceeds of approximately $4.6 million** through the company's aftermarket (or ATM) equity distribution program, and was awarded **$1.52 million** in **grant income** from Walloon Region.

VALUATION

Utilizing a financial model based on DCF methodology, which forecasts out to 2032, and uses a 10% discount rate (based on CAPM) and a 2% terminal growth rate, the indicated value of VNRX is **$7.83 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 +16.3% in 2021 as equity financings have helped fund the company's research & development costs and general corporate expenses. Thus far in 2022 (through March 31, 2022), shares outstanding have increased only 1.1%. 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	1Q 2022
Period ending	12/31/2018	12/31/2019	12/31/2020	12/31/2021	3/31/2022
ASSETS					
Cash and cash equivalents	13,427,222	16,966,168	19,444,737	20,581,313	23,732,379
Accounts receivable	-	-	7,118	12,510	72,371
Prepaid expenses	245,441	267,518	303,178	598,367	1,263,149
Other current assets	229,755	322,593	576,660	786,642	888,827
Total Current Assets	**13,902,418**	**17,556,279**	**20,331,693**	**21,978,832**	**25,956,726**
Property, plant and equipment	3,119,643	2,981,225	5,171,134	4,911,077	4,721,065
Operating lease right-of-use assets	-	381,483	326,085	383,551	830,257
Intangible assets	466,905	372,305	321,641	216,876	175,391
TOTAL ASSETS	**17,488,966**	**21,291,292**	**26,150,553**	**27,490,336**	**31,683,439**
Accounts payable	807,162	627,253	1,539,547	1,542,457	2,205,240
Accrued liabilities	923,034	2,168,588	3,491,740	3,841,013	3,538,881
Deferred revenue					10,000,000
Management and directors' fees payable	1,200	21,979	55,174	71,303	97,640
Current portion of long-term debt	416,553	647,569	841,319	797,855	1,333,316
Current portion of financing lease liabilitie	145,150	97,946	59,930	48,958	46,656
Current portion of operating lease liabiliti	-	257,244	179,624	171,166	249,051
Deferred grant income	-	-	-	-	-
Current portion of grant repayable	40,094	39,295	69,218	43,100	42,036
Total Current Liabilities	**2,333,193**	**3,859,874**	**6,236,552**	**6,515,852**	**17,512,820**
Long-term debt	1,984,262	2,195,278	2,606,885	2,270,767	2,031,875
Financing lease liabilities	720,013	607,708	601,967	511,086	486,690
Operating lease liabilities	-	131,875	151,828	217,305	594,392
Grant repayable	311,042	297,991	259,603	253,221	246,970
Non-Current Liabilities	**3,015,317**	**3,232,852**	**3,620,283**	**3,252,379**	**3,359,927**
TOTAL LIABILITIES	**5,348,510**	**7,092,726**	**9,856,835**	**9,768,231**	**20,872,747**
SHAREHOLDERS' EQUITY					
Common Stock	35,335	41,125	48,607	53,772	53,790
Additional paid-in capital	85,604,271	103,853,627	126,526,239	154,730,938	155,655,418
Accumulated other comprehensive incom	223,651	125,670	(59,978)	148,326	30,422
Accumulated deficit	(73,722,801)	(89,821,856)	(110,173,971)	(136,988,636)	(144,622,666)
Total VolitionRx Stockholders' Equity	**12,140,456**	**14,198,566**	**16,340,897**	**17,944,400**	**11,116,964**
Non-controlling interest	-	-	(47,179)	(222,295)	(306,272)
Total Stockholders' Equity	**12,140,456**	**14,198,566**	**16,293,718**	**17,722,105**	**10,810,692**
TOTAL LIABILITIES & STOCKHOLDERS' EC	**17,488,966**	**21,291,292**	**26,150,553**	**27,490,336**	**31,683,439**
Shares outstanding	35,335,378	41,125,303	48,607,017	53,223,761	53,790,261

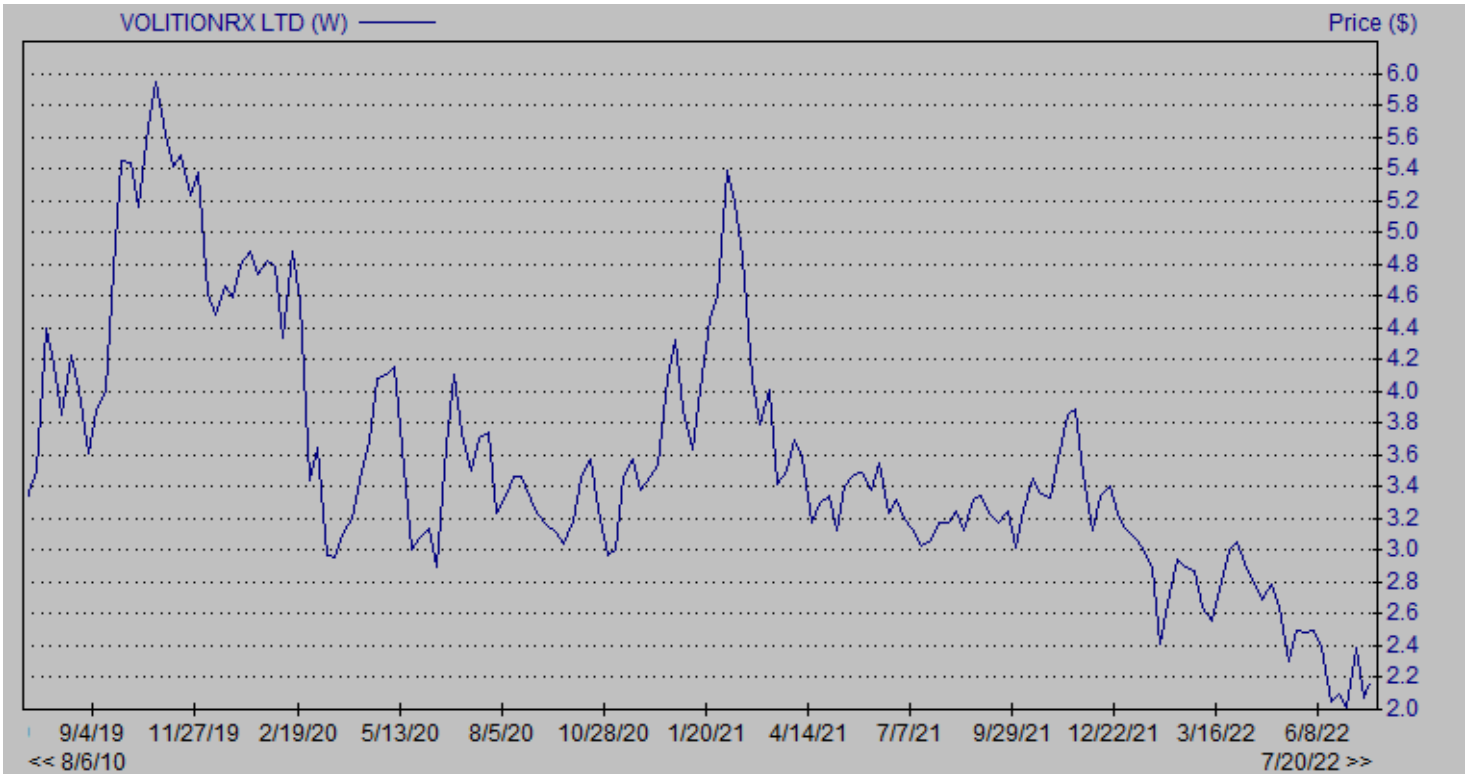
PROJECTED ANNUAL INCOME STATEMENTS

VolitionRx Limited Income Statement (in $US, except share and per share data)	2018 12/31/2018	2019 12/31/2019	2020 12/31/2020	2021 12/31/2021	2022 Est. 12/31/2022
Product	-	-	11,321	90,035	250,414
Agreement Fee (Nu Vet)					0
Service (Contract lab services)	-	16,204	0	0	280,254
Royalty (Research kits)	-	892	2,112	0	0
Total Revenues	**0**	**17,096**	**13,433**	**90,035**	**530,668**
Expenses					
Research and development	10,906,871	10,363,253	14,533,862	15,541,889	15,019,443
General and administrative	5,821,072	4,731,054	5,654,018	8,751,392	10,886,433
Sales and marketing	1,169,756	965,713	1,073,368	4,129,833	7,205,196
Total Operating Expenses	**17,897,699**	**16,060,020**	**21,261,248**	**28,423,114**	**33,111,073**
Loss Before Other Income	**(17,897,699)**	**(16,042,924)**	**(21,247,815)**	**(28,333,079)**	**(32,580,404)**
Grant income	-	155,031	635,513	1,522,533	0
Interest income	-	112,367	49,495	2,734	1,602
Interest (expense)	(110,924)	(126,572)	(129,799)	(155,803)	(171,663)
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**	**(170,061)**
Net Gain (Loss)	**(18,008,623)**	**(16,099,055)**	**(20,399,294)**	**(26,989,781)**	**(32,750,465)**
Net Gain (Loss) Non-Controlling Int.	-	-	(47,179)	(175,116)	(246,393)
Net Gain (Loss) - VNRX Stockholders	**(18,008,623)**	**(16,099,055)**	**(20,352,115)**	**(26,814,665)**	**(32,504,071)**
Basic and diluted loss per share	**(0.57)**	**(0.41)**	**(0.45)**	**(0.51)**	**(0.57)**
Wgted. Avg. Shares Out. - diluted	31,389,220	39,180,369	45,278,847	52,655,885	57,032,239

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 E 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	59,353	65,288	45,000	223,598
Agreement Fee	-	0	0	0	0	0
Service (Contract lab services)	0	60,254	65,000	75,000	80,000	280,254
Royalty (Research kits)	0	0	0	0	0	0
Total Revenues	**90,035**	**114,211**	**124,353**	**140,288**	**125,000**	**503,852**
Expenses						
Research and development	15,541,889	3,590,053	3,697,755	3,808,687	3,922,948	15,019,443
General and administrative	8,751,392	2,602,152	2,680,217	2,760,623	2,843,442	10,886,433
Sales and marketing	4,129,833	1,598,983	1,726,902	1,865,054	2,014,258	7,205,196
Total Operating Expenses	**28,423,114**	**7,791,188**	**8,104,873**	**8,434,364**	**8,780,648**	**33,111,073**
Loss Before Other Income	**(28,333,079)**	**(7,676,977)**	**(7,980,520)**	**(8,294,076)**	**(8,655,648)**	**(32,607,221)**
Grant income	1,522,533	0	0	0		0
Interest income	2,734	2	500	700	400	1,602
Interest (expense)	(155,803)	(41,032)	(42,263)	(43,531)	(44,837)	(171,663)
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)**	**(41,763)**	**(42,831)**	**(44,437)**	**(170,061)**
Net Gain (Loss)	**(26,989,781)**	**(7,718,007)**	**(8,022,283)**	**(8,336,907)**	**(8,700,084)**	**(32,777,281)**
Net Gain (Loss) Non-Controlling Int.	(175,116)	(83,977)	(52,050)	(54,092)	(56,448)	(246,567)
Net Gain (Loss) - VNRX Stockholde	**(26,814,665)**	**(7,634,030)**	**(7,970,233)**	**(8,282,815)**	**(8,643,636)**	**(32,530,714)**
Basic and diluted loss per share	**(0.51)**	**(0.14)**	**(0.15)**	**(0.14)**	**(0.14)**	**(0.57)**
Wgted. Avg. Shares Out. - diluted	52,655,885	53,775,096	54,175,096	59,889,382	60,289,382	57,032,239

HISTORICAL STOCK PRICE



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[i] Annals of Internal Medicine, August 2, 2011

[ii] Risk of Perforation After Colonoscopy and Sigmoidoscopy: A Population-Based Study, Journal of the National Cancer Institute, Volume 95, Issue 3, 5 February 2003, pages 230–236

[iii] https://www.healthline.com/health/colorectal-cancer-survival-rate