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Zacks Small-Cap Research

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VolitionRx Ltd (VNRX-NYSE American)

Nu.Q COVID-19 triage test and the **Nu.Q Vet assay are on track to generate revenues in 2021.**

A discounted cash flow (DCF) model that applies a 9.5% discount rate and a 2% terminal growth rate indicates a price target of $6.70 per share.

Current Price (08/14/20)	$3.46
Valuation	**$6.70**

OUTLOOK

VolitionRx continues to advance clinical studies in the cancer arena and now also for **COVID-19**.

Based on studies that detected an increase of nucleosomes in COVID-19 positive patients, a follow-up longitudinal study for the **Nu.Q COVID-19 triage test** is expected to be conducted in 2H 2020.

Proof-of-concept studies on **Nu.Q Vet assay** were very promising. Management expects to generate initial sales through the Texas A&M College of Veterinary Medicine.

Large-scale clinical trials on CRC and lung cancers (at the National University of Taiwan) are ongoing.

SUMMARY DATA

52-Week High	**$6.84**
52-Week Low	**$2.22**
One-Year Return (%)	**-4.02**
Beta	**1.72**
Average Daily Volume (shrs.)	**740,376**
Shares Outstanding (million)	**47.89**
Market Capitalization ($mil.)	**$165.7**
Short Interest Ratio (days)	**1.44**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**38**
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 2020 Estimate	**N/M**
P/E using 2021 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)
2018	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2019	0.0 A	0.0 A	17.1 A	0.0 A	17.1 A
2020	0.5 A	5.2 E	5.0 E	7.7 E	18.4 E
2021					154.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.17 A	-$0.15 A	-$0.14 A	-$0.11 A	-$0.57 A
2019	-$0.12 A	-$0.11 A	-$0.10 A	-$0.09 A	-$0.41 A
2020	-$0.14 A	-$0.12 A	-$0.11 E	-$0.11 E	-$0.48 E
2021					-$0.44 E

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

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EXECUTIVE SUMMARY

VolitionRx is engaged in **multiple epigenetic projects** coupled with **several corporate initiatives**. The company is involved with developing numerous **blood-based clinical assays**, primarily **focused on** detecting certain **cancers** (CRC, lung, haematological), along with one targeting canine cancer. Management also saw an opportunity to utilize the company's proprietary Nu.Q™ platform to develop a clinical assay to aid in the treatment regimen of **COVID-19** patients.

Management's front-burner projects are the **Nu.Q COVID-19 triage test** and the **Nu.Q Vet assay for cancer detection in canines**, both of which are expected to start generating revenues in 2021. Management's revenue expectations are based on achieving certain milestones, namely:

1) successfully completing a clinical study on Nu.Q Vet for canine cancers and registering the product with the USDA and
2) successfully completing a longitudinal study and obtaining the European CE-Mark for the COVID-19 prognostic triage test

VolitionRx reported **second quarter results** on August 13, 2020**.**

- Business update
  - **Acquiring 10,000 square-foot building** (Silver One) in close proximity to the company's R&D center in Isnes, Belgium
    - To be renovated to serve as a production hub, service lab and facility for contract research. Management expects the facility to be operational by October
    - As a production facility, expect to produce components (recombinant nucleosomes, reagents etc.) in house, thereby securing the company's supply chain while simultaneously lowering costs
    - Potential revenues could be generated by selling the components to and by processing samples for external parties
- **Assay closest to commercialization is Nu.Q Vet**
  - Two abstracts are to be presented at the virtual Veterinary Cancer Society Meeting in October
  - Clinical study on canine cancer in the works (most likely with a few hundred subjects). The goal is to register the product with the USDA so that initial sales can be generated, initially through Texas A&M College of Veterinary Medicine, which is VolitionRx's collaborating partner who is conducting the study
- **Stronger balance sheet**
  - Cash and cash equivalents expanded sequentially from $12 million to over $20 million
  - Working capital improved sequentially from $8.5 million to $17.7 million
- Shares outstanding increased 13.2% sequentially from 41.2 million to 46.7 million shares
- Due to VolitionRx's inclusion into two **Russell Microcap** Indexes in June, the iShares Russell 2000 ETF now owns 485,907 shares of VNRX or 1.0% of the shares outstanding

Due to the number and intricacy of ongoing projects, an **outline** of projects, initiatives and milestones (both achieved and expected) follows in order to better communicate the company's fundamental attributes and prospects.

OUTLINE OF PROJECTS, INITATIVES AND KEY MILESTONES

- **Highlights of 2019**
  - completed two-year project of re-engineering the Nu.Q™ clinical assay platform through an optimization program that **migrated to a magnetic bead-based chemiluminescent platform**
  - formed **Volition Veterinary Diagnostics** subsidiary in June 2019
    - signed collaboration agreement with Texas A&M College of Veterinary Medicine & Biomedical Sciences in October 2019
      - in exchange for 12.5% ownership of the veterinary subsidiary, Texas A&M will conduct numerous clinical studies testing whether VolitionRx's blood tests can detect canine cancers
- **Highlights of first half of 2020**
  - **acquired Octamer GmbH** on January 10, 2020
    - now has **in-house capability to manufacture key components of Nu.Q platform**, including **recombinant nucleosomes** (used as calibrants) and epigenetic reagents, such as histones, octamers and DNA templates
  - **Nu.Q COVID-19 triage test** - a prognostic blood-based assay for the severity of COVID-19
    - proof-of-concept study: elevated levels of nucleosomes of positive COVID-19 patients AUC 98.7%
    - proof-of-concept study: correlation between nucleosome level and severity of the disease
  - presented **three abstracts at ASCO** (American Society of Clinical Oncology) 2020 in May, demonstrating the robustness and utility of the Nu.Q™ platform
    - first data on **Nu.Q™ Capture** as a sample-enrichment tool
    - Nu.Q™ assay performance in **lung cancer**
    - Nu.Q™ assay performance in **haematological cancers**
  - VolitionRx was added to both the **Russell 3000** and **Russell Microcap Indexes** effective June 26, 2020
- **Management's expectations for next 12 months (2H/2020-1H/2021)**
  - **Nu.Q COVID-19 triage test**
    - longitudinal clinical study is expected to be completed by the end of 2020, along with release of clinical data
    - obtain European CE-Mark certification by the end of 2020
  - **Nu.Q Vet assay for cancer detection in canines** - first non-human application of Nu.Q epigenetic platform
    - report final clinical trial results
    - anticipate launch **Nu.Q Vet assay for cancer detection in canines**, initially through Texas A&M College of Veterinary Medicine (4Q/2020-1H/2021)
    - prospects of nation licensing agreements in 2021- 2022 for national distribution
  - Licensing efforts
    - progress on 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 in China**
    - the agreement further allows for the negotiation of an exclusive licensing agreement for Fosun to distribute Volition's Nu.Q tests on the LUMIART-II System in China
  - Ongoing large-scale studies for colorectal cancer and lung cancer in Asia and U.S.
  - **Nu.Q™ Capture platform** – sample enrichment tool
    - initiate studies on Nu.Q Capture's enriched samples with mass spectrometry and by sequencing for the purpose of **identifying tumors** and other mutations
    - plans to advance the development of Nu.Q™ Capture using mass-spectrometry and/or sequencing in order to **identify new biomarker targets**

- During the COVID-19 pandemic, VolitionRx has been able to keep the company's lab fully operational by maintaining social distancing in its 20,000 sq. ft. facility in Belgium. Non-laboratory staff members are working remotely.

RECENT NEWS

Second Quarter 2020 Financial Results

On August 13, 2020, VolitionRx reported financial results for the second quarter ending June 30, 2020. Total revenues were $5,194, of which $3,322 was product revenue and $1,872 were royalties.

Operating expenses increased 26.5% from $4.12 million to $5.22 million. R&D expenses increased 40.9% to approximately $3.49 million, primarily related to higher antibody costs, sample costs, laboratory expenses and personnel expenses. G&A expenses increased only 7.2% to approximately $1.51 million, primarily driven by higher legal and professional fees, which were somewhat offset by lower travel costs. Sales and marketing expenses declined 9.3% as an increase in direct marketing professional fees was more than offset by lower travel and personnel costs.

For the second quarter, VolitionRx reported a net loss of $5.04 million (or $0.12 per diluted share) versus a net loss of approximately $4.16 million (or $0.11 per diluted share) in the comparable quarter last year.

As of June 30, 2020, working capital was approximately $17.7 million, 29% above the $13.7 million on December 31, 2019. Shares outstanding have increased by 13.5% to 46,658,554 shares from 41,125,303 shares on December 31, 2019.

COVID-19 Operational Update – July 30, 2020 LD Micro Presentation

During the COVID-19 pandemic, VolitionRx has been able to keep the company's lab fully operational by maintaining social distancing in their 20,000 sq. ft. facility in Belgium and with non-laboratory staff working remotely. Most of the company's clinical studies are retrospective with the samples having already been collected. In the Taiwan studies, sample collections for colorectal cancer (CRC) and lung cancer studies are ongoing, and the project with Fosun Pharma continues to proceed. In addition, the development of the Nu.Q COVID-19 triage product was initiated.

Three Abstracts Presented at ASCO 2020

VolitionRx presented three abstracts at American Society of Clinical Oncology's Scientific program (ASCO 2020) held virtually between May 29 and May 31.

- **Nu.Q™ Capture** performance in colorectal cancer samples
  - enrichment of circulating tumor nucleosomes and tumor DNA
- Nu.Q™ assay performance **in lung cancer** (n=142, AUC of 88%)
- Nu.Q™ assay performance in **haematological cancers** (n=333, AUC of 91%)

E13534: Data from a pilot study was presented that demonstrated that **Nu.Q Capture** separated short circulating tumor nucleosomes and circulating tumor DNA (ctDNA) in colorectal cancer samples from long healthy nucleosomes. Chromosomes from healthy cells differ from those in cancer cells based on the genetic sequence and protein structure. The key difference between the DNA of the healthy nucleosomes (background cell free DNA) is slightly longer than the ones from tumor cells and ctDNA. The Nu.Q Capture technology is designed to remove long healthy nucleosomes so that the sample has enriched cancer-derived nucleosomes, which have cancer specific mutations. The **enriched sample** allowed for a more accurate measurement of cancer

nucleosomes and ctDNA. In addition, after isolation, the sample can undergo mass spectrometry to help identify biomarker targets or the DNA can be sequenced for diagnostic applications. A more detailed explanation of Nu.Q Capture is in the Nu.Q Capture Technology Section below**.** Also, there is a 4-minute YouTube video that explains the study in greater detail: https://youtu.be/ypzzfpnvC5w

E15542: In a pilot study of 142 subjects (from 45 healthy, 44 lung cancer and 53 COPD participants), Nu.Q assays discriminated between **lung cancer** and healthy subjects with an AUC of 88%. In addition, Nu.Q assays discriminated between lung cancer and **COPD** (Chronic Obstructive Pulmonary Disease) with an AUC of 85%.

E20078: In a pilot study of 62 healthy subjects (control group) and 329 patients (271 solid tumor, 25 NHL, 25 AML and 8 ALL), **levels of the histone H3.1 isoform (Nu.Q™-H3.1) were elevated in patients diagnosed with certain haematological cancers**. The median Nu.Q™-H3.1 levels observed in patients with **Non Hodgkin Lymphoma** (NHL), **Acute Myeloid Leukemia** (AML) and **Acute Lymphocytic Leukemia** were 276 ng/ml, 284 ng/ml and 585ng/ml, respectively. The median nucleosome level in 62 healthy subjects was 40ng/ml (the highest being 198ng/ml). The **AUC was 91%** for all patients diagnosed with NHL, AML or ALL (n=54) vs healthy subjects with a sensitivity of 74% at 95% specificity. Often with non-specific symptoms, blood cancers are generally difficult to detect. The results are very encouraging since elevated levels were revealed by the Nu.Q assays in patients diagnosed with different types of hematological cancers. The study indicates that Nu.Q technology may be a useful diagnostic tool, and further study is warranted.

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 **will 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.

Public Offering of Common Stock

On May 22, 2020, VolitionRx closed a public offering of 5,019,750 shares priced at $2.75 per share. **Gross proceeds were $13.8 million**. Net proceeds will be used for continued product development, clinical studies, product commercialization, working capital and general corporate purposes, including potential strategic acquisitions.

Under an Equity Distribution Agreement (aka At The Market equity offering program or ATM) with Oppenheimer & Co., VolitionRx issued 436,372 shares under this shelf registration statement during the first half of 2020. **Net proceeds were approximately $1.7 million**. Subsequent to the quarter end, approximately an additional 1.2 million shares were sold under the ATM. **Net proceeds were approximately $4.7 million**.

Nu.Q COVID-19 TRIAGE ASSAY – A NEW OPPORTUNITY

VolitionRx is seeking to develop a COVID-19 triage test that is to be performed as a companion test **after** a patient has tested positive through one of the many front-line diagnostic PCR (polymerase chain reaction) screening tests approved under the Emergency Use Authorization (EUA) authority of the FDA. The purpose is to develop a **prognostic predictor** of the severity of the COVID-19 disease in a given patient.

Management believes that Nu.Q-developed blood tests for circulating nucleosome debris and NETs production may be able to provide early insight into and predict the evolution of the severity of the disease in COVID positive patients. Volition is investigating if Nu.Q epigenetic assays are able to **triage patients** into those that have a higher probability of requiring higher levels of therapeutic treatment in preparation for the onset of serious symptoms (e.g. immune suppressors, hospitalization, oxygen, ventilation, intubation, etc.) versus those that do not have a likelihood of developing serious symptoms, and therefore, not needing critical care. Those patients with low levels of nucleosome could be sent home to self-isolate and be monitored. Currently, doctors wait for the onset of more serious symptoms before requiring hospitalization, wasting valuable time that could be used to treat patients sooner and more effectively in the hospital.

By detecting elevated levels of nucleosomes and Neutrophil Extracellular Traps (NETs) BEFORE the onset of serious symptoms, management believes a Nu.Q assay has the potential to identify patients that ultimately will require hospitalization. In addition, not only are these elevated levels are anticipated to precede the actual onset of serious symptoms, but also the actual level is believed to serve as a **quantitative risk stratification tool**. It is supposed that more timely detection would lead to earlier appropriate treatment, which, in turn, would lead to better patient outcomes. Also, effective triaging of patients would result in a more efficient use of critical care resources.

If it is demonstrated that a VolitionRx Nu.Q assay is a robust prognostic predictor of the impending severity of the disease, the Nu.Q prognostic test would be administered immediately after a patient tests positive. However, the **potential market** would be larger, since not only would every patient be administered the initial triage test upon testing positive, but also each patient would be subjected to a series of potentially daily assays until the patient finally tests negative.

VolitionRx is proceeding with the process to determine the prognostic potential of a COVID-19 triage test, which was developed on the company's Nu.Q epigenetic platform.

The participants in the **first proof-of-concept study** were 34 PCR COVID-19 positive subjects and 50 control subjects located in Isnes, Belgium. The preliminary study revealed that **PCR positive subjects exhibited elevated levels of nucleosomes relative to healthy control subjects**. The **AUC** (Area Under the Curve) **for a single Nu.Q assay was 98.7%** for PCR positive COVID patients versus control subjects with a sensitivity of 100% at 94% specificity. In other words, almost everyone who tested positive for COVID-19 had elevated nucleosomes. A second Nu.Q assay also revealed promising results with an AUC of 86.2%.

A **follow-up proof-of-concept study demonstrated stratification.** Two independent cohorts of COVID-19 positive patients at University Hospital Liege, Belgium and at the German Heart Center in Munich, Germany, were administered quantitative nucleosome immunoassays. It was found that the highest levels of nucleosome debris and NETs production (which is a result of a ramp-up of the immune system) were found in patients in the ICU that required ventilation. In addition, both histone 3.1 variant and citrullinated nucleosomes increased with disease severity. Importantly, there was a **correlation between the level of nucleosome elevation and the severity of the disease**. Healthy control subjects had the lowest levels nucleosome debris.

The results of these proof-of-concept clinical studies were submitted for peer review in July. The associated article, "Circulating Nucleosomes as potential prognostic markers for COVID-19 disease severity," will be available on bioRxiv.org soon.

Management is **now focused on larger longitudinal studies** in order to **determine the lead time** between the realization of high levels of circulating nucleosome debris (and NETs production) and the onset of severe symptoms. Therefore, management believes that the demonstrated correlation implies strong prognostic and that circulating nucleosomes could serve as a biomarker for disease severity in COVID-19 positive patients. The longitudinal studies are expected to be completed by the end of 2020.

As the longitudinal studies are being conducted, management intends to complete the CE-Mark certification process in Europe. Ideally, the company could fulfill the requirements of the CE Mark and have completed longitudinal clinical studies by year-end, setting the stage for FDA approval in 2021. A novel **patent has been filed already for this COVID-19 triage test**.

VOLITION VETERINARY DIAGNOSTICS - CANINE CANCER

On June 3, 2019, VolitionRx formed **Volition Veterinary Diagnostics Development LLC**, which will focus on the veterinarian diagnostics market. Canine cancer represents a sizeable market as approximately 6.0 million cases of canine cancer are diagnosed each year in the U.S.[i] compared to 1.76 million human cancers.[ii] Roughly 25% of dogs develop cancer at some point in their lives, most often at an age between 8 and 10 years old. With pricing likely to be in the $100-to-$200 per test range, the canine cancer opportunity could be in the hundreds of millions of dollars.

Currently, there is a scarcity of accurate, simple and affordable cancer screening tests in veterinary medicine. In response to the initial symptoms of lethargy, lesions and/or soreness, a veterinarian grapples with a definitive diagnosis of the various possibilities (inflammation, infection, cancer etc.). For an infection, the line of treatment would be to prescribe an antibiotic and then wait-and-see if the dog's condition improves. The screening methodology for cancer involves taking a scan or a biopsy, which is expensive and not without risk, since anesthesia is necessary, in some cases. A front-line blood test that could rule-in or rule-out cancer would aid the diagnosis process and allow for a more effective and less expensive treatment regimen.

Management's goal is to provide all veterinarian clinics with blood tests that can help identify canine cancers early. **Management intends to expand from the current one biomarker** in the company's current portfolio, **to several biomarkers in order to create a panel** in order to increase the accuracy of a single assay.

On October 25, 2019, VolitionRx **partnered with the Texas A&M College of Veterinary Medicine** & Biomedical Sciences. In exchange for 12.5% ownership of the veterinary subsidiary, Texas A&M University will conduct numerous clinical studies that will test whether VolitionRx's blood tests can detect canine cancer.

The first canine clinical study with Texas A&M University was completed in April 2020. In the **proof of concept study,** a single Nu.Q Vet assay detected almost 70% of two cancers (Canine Hemangiosarcoma and Canine Lymphoma, which account for almost a third of all canine cancers). At a specificity of 90%, **AUCs were 84.5% and 83.1%** for cancer versus healthy.

Management believes that a Nu.Q Vet test for the diagnosis of canine cancer could potentially be on the market in the fourth quarter of 2020. Initially, management plans to sell the canine cancer test through the Texas A&M College of veterinary medicine. Then, in 2021, with assistance from Texas A&M, VolitionRx will pursue registering the product with the USDA (United States Department of Agriculture). Management believes that a canine cancer test could be a relatively fast-moving program given the less-stringent USDA regulatory pathway for animal diagnostics versus FDA's PMA or 510k. Once registered, the company intends to pursue a licensing agreement with one or more animal diagnostics companies in order to launch the product nationwide.

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 haematological cancers.

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[iii]). 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%[iv]). 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%.[v] 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.

VolitionRx has a substantial IP portfolio with **50 patents**, including eight in the U.S., 10 in Europe and an additional 32 worldwide. The company has 99 patent applications pending.

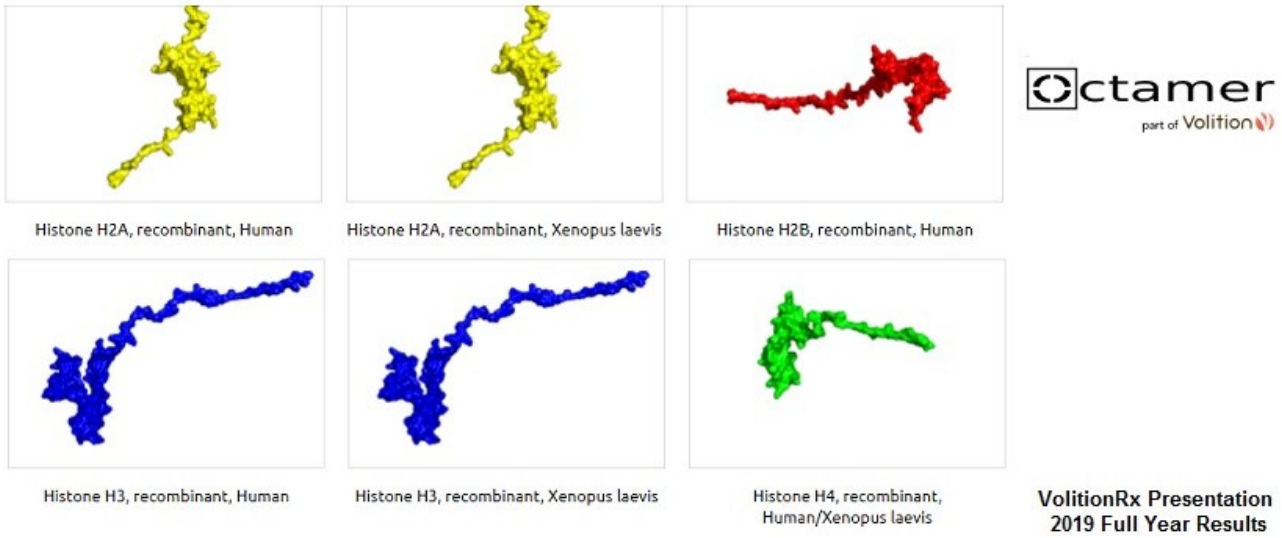
The company's **principal research and development center** is located in Isnes, **Belgium**. Opened in 2017, the **custom-designed facility** has 20,000 sq. ft. of office and R&D space, of which 10,000 square feet is devoted to the laboratory. Here, the company has the ability to conduct R&D and clinical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



VolitionRx Presentation May 13, 2020

VOLITION GERMANY GmbH (fka OCTAMER)

On January 10, 2020, Volition **acquired Octamer GmbH** for €650,000 (approximately **$725,000**, of which $412,404 (€371,736) was in cash and 73,263 in restricted common shares of VNRX). Located in Gräfelfing, Bavaria, Octamer is an epigenetic reagent company. This **strategic acquisition** provided Volition with the in-house capability to **manufacture recombinant nucleosomes**, which are used as calibrants and are key components of Volition's Nu.Q platform. In addition, Octamer manufactures and sells **other epigenetic reagents** used in epigenetic research and drug discovery, such as histones, octamers and DNA templates. Not only does the acquisition help secure VolitionRx's supply chain, it also can allow the pace assay development work to increase. Dr. Adrian Schomburg, founder and CEO of Octamer, joined VolitionRx's Scientific Advisory Board. In the first quarter of 2020, Octamer GmbH was **renamed Volition Germany GmbH**.



Nu.Q™ PROCESS RE-ENGINEERED

In early 2020, VolitionRx completed a project that **re-engineered the Nu.Q assay platform**. Previously, Volition's assays utilized a plate format, a process that utilizes high protein-binding plates and requires a six-hour incubation period. After the re-engineering project, assays now use a **magnetic particle-based assay format** that gives a chemiluminescent endpoint which requires less than two hours. Luminescent assays are known to be very sensitive and have a wide dynamic range. Therefore, there has been a **step-change improvement** in analytical performance in terms of sensitivity, throughput and reproducibility, along with improved specificity and reduced background noise, all of which translates into improved clinical performance. In addition, the matrix was changed from serum to plasma, which enhanced accuracy (through an improved noise-to-signal ratio).

The magnetic particle-based chemiluminescent assay format provides at least a **10-fold improvement in analytical sensitivity** compared to the prior plate format due to the benefits of using blood plasma, which aided in reducing interferences. In addition, the new format **cuts the turnaround time** of test results with the time required to process a test having been reduced from six hours to one hour and 20 minutes. Obviously, this enables a much **higher throughput**. **Reproducibility** of test results is excellent, which improved from below 10% to just below 3%.

The re-engineered Nu.Q assay format can be used on a wider range of commercial, fully-automated platforms, and the FDA has approved the automated immunoassay analyzer with all of the above improvements for clinical use in the U.S. and Europe. **Through the first quarter of 2020**, VolitionRx

has **developed eight different bead-based Nu.Q assays** on the new, re-engineered assay platform.

Even under the new re-engineered the Nu.Q assay platform, a few assays will continue to utilize the plate process, the triage tests and research-use kits, to name a couple.

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 will include **1,200 participants** receiving low-dose CT scan, 1,000 of which have lung cancer. The study could 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. VolitionRx currently expects to announce preliminary data from this study in 2H2020. As of July 2020, **more than 30% of the 1,200 samples have been collected**, but the COVID-19 pandemic is impacting the same gathering process

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 several large-scale, ongoing colorectal cancer studies. 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. As of July 2020, **more than 50% of the samples have been collected**, but the COVID-19 pandemic is impacting the same gathering process.

CRC Trial Timelines of VolitionRx

Institution	Condition	Sample Collection	Cohort	Timing
Early Detection Research Network of the U.S. National Cancer Institute (EDRN)	Colorectal Cancer	9,000 Prospective, 4,600 Retrospective	13,500 + Screening Population	Collection Ongoing to 2020.
National Taiwan University	Colorectal Cancer	Prospective	5,000 Asymptomatic Patients	Collection Ongoing to 2021.
National Taiwan University	Colorectal Cancer	Prospective	2,000 Symptomatic Patients	Collection Ongoing to 2021.

VolitionRx 10-K 2018

The target number of samples for the prospective sampling in the EDRN trial (in the table above) is now at a minimum of 6,000 subjects. Given the shutdowns and lockdown restrictions in the U.S., the COVID-19 pandemic has slowed rate of collection, and at times, halted collections altogether. Due to slower-than-expected collections, management anticipates that the trial will be extended

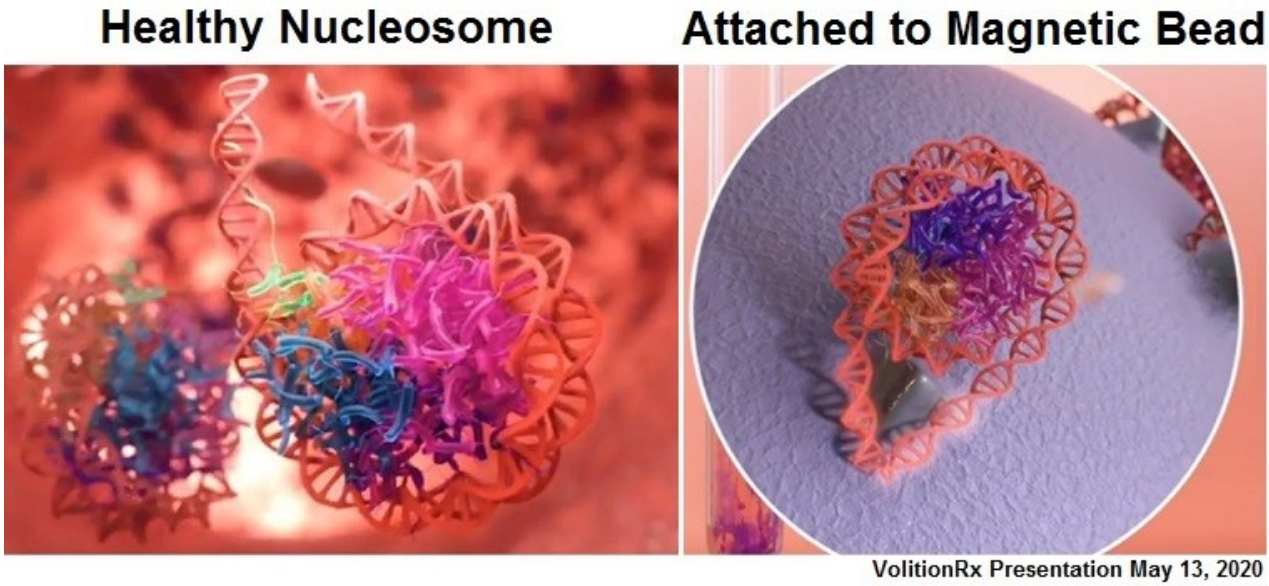
HEMATOPOIETIC (BLOOD-BORNE) CANCER

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-Hodgkins 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**, which is now expected to occur in the first quarter of 2021. 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.

SHANGHAI FOSUN LONG MARCH – LICENSING EFFORT IN CHINA

On March 28, 2019, VolitionRx signed a memorandum of understanding (MOU) with **Shanghai Fosun Long March Medical Science** Co, Ltd (a wholly-owned subsidiary of Fosun Pharma 600196.SH; 02196.HK). So far, the MOU has resulted in two collaborative projects:

- The effort to transfer VolitionRx's Nu.Q magnetic particle-based assays onto Fosun's open-access LUMIART-II fully-automated, high throughput system, which is commercialized in China
- The initiation of lung cancer studies in China, along with plans to start to other studies, one in colorectal cancer and the other in ovarian cancer

Subsequently, on May 8, 2020, two companies signed a contract to **adapt and transfer VolitionRx's Nu.Q magnetic particle-based assays onto Fosun's open-access LUMIART-II** Automated Chemiluminescence Immunoassay platform. The agreement further allows for the negotiation for an exclusive licensing agreement for Fosun to distribute Volition's Nu.Q tests on the LUMIART-II System in China. Then, in the third quarter of 2019, VolitionRx and Fosun launched **clinical studies** using Nu.Q assays to screen **for lung cancer**, one being a small-scale study with Shanghai Fosun Long March and the other being a large-scale study with the National Taiwan University. Other studies with Fosun are expected in the areas of colorectal cancer and ovarian cancer

Also, in the third quarter of 2019, VolitionRx sold research-use only kits for the clinical studies, along with a provision for contract research services. As a result, the company recorded its **first revenues from sales** during that quarter.

INSIDER AND INSTITUTIONAL OWNERSHIP

As of August 3, 2020, insiders held 38% of the shares outstanding. John Cameron (CEO) owned 2,184,170 shares (4.6% of the shares outstanding), Dr. Martin (Dill) Faulkes (Executive Chairman) beneficially held 1,926,940 shares (4.0), Guy Innes (Non-Executive Director) owned 1,230,150 shares (2.6%) and Rodney Rootsaert (Corporate Secretary) owned 1,028,120 shares (2.1%). In addition, Cotterford Co. Ltd beneficially owns 11,637,844 shares or 23.4% of the common stock in the company.

Institutional investors own 8.73% of the shares outstanding of VolitionRx. Lagoda Investment Management was the largest holder with 3.9% of the shares outstanding. Other major institutional holders include iShares Russell 2000 ETF (1.0%), Geode Capital Management (0.7%) and the Vanguard Group (0.7%).

VALUATION

Utilizing a financial model based on DCF methodology, which forecasts out to 2030, and uses a 9.5% discount rate (based on CAPM) and a 2% terminal growth rate, the indicated value of VNRX is **$6.70 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.

- 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)	2016	2017	2018	2019	2Q 2020
Period ending	12/31/2016	12/31/2017	12/31/2018	12/31/2019	6/30/2020
ASSETS					
Cash and cash equivalents	21,678,734	10,116,263	13,427,222	16,966,168	21,305,266
Accounts receivable	-	-	-	-	3,223
Prepaid expenses	165,927	248,661	245,441	267,518	585,313
Other current assets	166,887	202,295	229,755	322,593	525,013
Total Current Assets	**22,011,548**	**10,567,219**	**13,902,418**	**17,556,279**	**22,418,815**
Property, plant and equipment	2,119,027	3,480,782	3,119,643	2,981,225	3,265,025
Operating lease right-of-use assets	-	-	-	381,483	234,095
Intangible assets	602,193	576,397	466,905	372,305	328,703
TOTAL ASSETS	**24,732,768**	**14,624,398**	**17,488,966**	**21,291,292**	**26,246,638**
Accounts payable	281,179	351,735	807,162	627,253	1,414,266
Accrued liabilities	1,439,275	1,278,428	923,034	2,168,588	2,333,253
Management and directors' fees payable	81,057	35,397	1,200	21,979	10,499
Current portion of long-term debt	30,655	443,908	416,553	647,569	692,715
Current portion of financing lease liabilities	119,016	139,084	145,150	97,946	54,276
Current portion of operating lease liabilities	-	-	-	257,244	163,516
Deferred grant income	45,510	-	-	-	-
Current portion of grant repayable	36,804	41,930	40,094	39,295	39,321
Total Current Liabilities	**2,033,496**	**2,290,482**	**2,333,193**	**3,859,874**	**4,707,846**
Long-term debt	432,027	1,312,785	1,984,262	2,195,278	1,914,207
Financing lease liabilities	889,810	874,684	720,013	607,708	580,787
Operating lease liabilities	-	-	-	131,875	78,495
Grant repayable	202,325	188,579	311,042	297,991	302,106
Non-Current Liabilities	**1,524,162**	**2,376,048**	**3,015,317**	**3,232,852**	**2,875,595**
TOTAL LIABILITIES	**3,557,658**	**4,666,530**	**5,348,510**	**7,092,726**	**7,583,441**
SHAREHOLDERS' EQUITY					
Common Stock	26,126	26,519	35,335	41,125	46,660
Additional paid-in capital	62,287,252	65,774,870	85,604,271	103,853,627	118,915,549
Accumulated other comprehensive income	(193,297)	(129,343)	223,651	125,670	425,276
Accumulated deficit	(40,944,971)	(55,714,178)	(73,722,801)	(89,821,856)	(100,708,942)
Total VolitionRx Stockholders' Equity	**21,175,110**	**9,957,868**	**12,140,456**	**14,198,566**	**18,678,543**
Non-controlling interest	-	-	-	-	15,346
Total Stockholders' Equity	**21,175,110**	**9,957,868**	**12,140,456**	**14,198,566**	**18,663,197**
TOTAL LIABILITIES & STOCKHOLDERS' EQUITY	**24,732,768**	**14,624,398**	**17,488,966**	**21,291,292**	**26,246,638**
Shares outstanding	26,126,049	26,519,394	35,335,378	41,125,303	46,659,554

PROJECTED INCOME STATEMENTS

VolitionRx Limited

Income Statement (in $US, except share and per share data)	2016 12/ 31/ 2016	2017 12/ 31/ 2017	2018 12/ 31/ 2018	2019 12/ 31/ 2019	2020 E 12/ 31/ 2020
Product	-			-	11,126
Service (Contract lab services)	-			16,204	1,000
Royalty (Research kits)	-			892	6,312
Total Revenues	**0**	**0**	**0**	**17,096**	**18,438**
Expenses					
Research and development	7,904,988	8,906,006	10,906,871	10,363,25	15,010,24
General and administrative	4,177,513	5,376,500	5,821,07	4,731,05	6,321,16
Sales and marketing	347,712	763,407	1,169,756	965,713	934,66
Total Operating Expenses	**12,430,213**	**15,045,913**	**17,897,699**	**16,060,020**	**22,266,070**
Loss Before Other Income	**(12,430,213)**	**(15,045,913)**	**(17,897,699)**	**(16,042,924)**	**(22,247,632)**
Grant income	-		-	155,031	98,870
Interest income	-		-	112,367	60,155
Interest (expense)	(20,378)	(73,133	(110,924)	(126,572	(96,383)
Gain on disposal of fixed assets	-		-	-	93,202
Other income (expense)	545,313	349,839	-	(196,957)	0
Total Other Income (Expenses)	**524,935**	**276,70**	**(110,924)**	**(56,131)**	**155,844**
Net Loss	**(11,905,278)**	**(14,769,207)**	**(18,008,623)**	**(16,099,05**	**(22,091,78**
Net Loss - Non-Controlling Interest					
Net Loss - VolitionRx Stockholders					
Basic and diluted loss per share	**(0.52)**	**(0.56)**	**(0.57**	**(0.41**	**(0.48**
Wgted. Avg. Shares Out. - diluted	23,049,089	26,389,580	31,389,220	39,180,369	45,769,476

VolitionRx Limited

Income Statement (in $US except share and per share data)	2019 12/31/2019	1Q 2020 3/31/2020	2Q 2020 6/30/2020	3Q E 2020 9/30/20120	4Q E 2020 12/31/2020	Estimate 2020 12/31/2020
Product	892	304	3,322	3,000	4,500	11,126
Service (Contract lab services)	-	-	-	-	1,000	1,000
Royalty (Research kits)	16,204	240	1,872	2,000	2,200	6,312
Total Revenues	**17,096**	**544**	**5,194**	**5,000**	**7,700**	**18,438**
Expenses						
Research and development	10,363,253	3,894,966	3,492,845	3,723,472	3,898,956	15,010,240
General and administrative	4,731,054	1,703,522	1,508,836	1,539,013	1,569,793	6,321,164
Sales and marketing	965,713	273,954	215,891	220,209	224,613	934,667
Total Operating Expenses	**16,060,020**	**5,872,442**	**5,217,572**	**5,482,694**	**5,693,362**	**22,266,070**
Loss Before Other Income	**(16,042,924)**	**(5,871,898)**	**(5,212,378)**	**(5,477,694)**	**(5,685,662)**	**(22,247,632)**
Grant income	155,031	7,924	90,946	0	0	98,870
Interest income	112,367	38,414	7,741	9,500	4,500	60,155
Interest (expense)	(126,572)	(33,779)	(22,604)	(20,000	(20,000	(96,383)
Gain on disposal of fixed assets	0	0	93,202	0	0	93,202
Other income (expense)	(196,957)	0	0	0	0	0
Total Other Income (Expenses)	**(56,131)**	**12,559**	**169,285**	**(10,500)**	**(15,500**	**155,844**
Net Loss	**(16,099,055)**	**(5,859,339)**	**(5,043,093)**	**(5,488,194)**	**(5,701,162)**	**(22,091,788)**
Net Loss - Non-Controlling Interest	-	9,567	5,779			15,346
Net Loss - VolitionRx Stockholders	**(16,099,055)**	**(5,849,772)**	**(5,037,314)**	**(5,488,194)**	**(5,701,162)**	**(22,076,442)**
Basic and diluted loss per share	**(0.41)**	**(0.14)**	**(0.12)**	**(0.11)**	**(0.11)**	**(0.48)**
Wgted. Avg. Shares Out. - diluted	39,180,369	41,197,125	43,414,318	48,434,068	50,032,392	45,769,476

HISTORICAL STOCK PRICE



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