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Zacks Small-Cap Research

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VolitionRx Ltd (NYSE: VNRX)

VNRX: Highlights of Capital Markets Day (Nu.Q NETs & Nu.Q Vet); Heska being acquired by Mars increases Nu.Q Vet distribution footprint; 13 million share offering completed to help fund management's initiatives

A discounted cash flow (DCF) model that applies a 10% discount rate and a 2% terminal growth rate indicates a price target of $4.30 per share.

Current Price (06/22/23)	$1.55
Valuation	**$4.30**

OUTLOOK

Volition's **Nu.Q Vet Cancer Test** being launched by Supply Agreement partners**: IDEXX, Heska/Mars, SAGE and others.**

Clinical paper provides **new indication of monitoring** for Nu.Q Vet Cancer Test

Heska's **European launch** and **IDEXX's international launches** are anticipated in second half of 2023.

$6.5 million milestone payment from Heska expected during second quarter of 2023

SUMMARY DATA

52-Week High	**$2.73**
52-Week Low	**$1.31**
One-Year Return (%)	**-25.96**
Beta	**1.66**
Average Daily Volume (shrs.)	**134,588**
Shares Outstanding (million)	**76.1**
Market Capitalization ($mil.)	**$118.0**
Short Interest Ratio (days)	**5.3**
Institutional Ownership (%)	**10.4**
Insider Ownership (%)	**10.1**
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 A
2021	25.5 A	24.8 A	25.5 A	14.2 A	91 A
2022	114 A	40 A	33 A	120 A	306 A
2023	115 A	285 E	545 E	1,225 E	2,205 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	-$0.14 A	-$0.13 A	-$0.55 A
2023	-$0.15 A	-$0.13 E	-$0.11 E	-$0.10 E	-$0.48 E

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

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RECENT EVENTS

Annual Capital Markets Day

On May 11, 2023, VolitionRx conducted the company's Annual Capital Markets Day. The presentations included the **current status and prospects of Nu.Q NETs** and **Nu.Q Vet**, the two pillars of the company that are entering the commercialization phase. Volition's blood tests (assays)

Low cost (less than $100), routine (adaptable to many platforms) and accessible (multiple agreements for product distribution). One of management's utmost commercialization efforts involves **expanding the distribution channels** for the company's blood assays. During the Capital Markets Day, the company provided the **slide below showcasing the platforms** specifically targeted for processing the company's assays, along with the time required to process a blood sample. In addition, the can be processed at regional laboratories, which require longer periods of time.



VolitionRx Capital Markets Day Presentation May 11, 2023

Nu.Q NETs

The **Nu.Q NETs** presentation **focused on sepsis**, a disease that accounts for over 50 million cases and over 11 million deaths worldwide. There are more cases of sepsis per 100,000 population (377 cases) in the U.S. and Europe than cancer (332), stroke (223) or heart attacks (208).

There is an **excellent presentation discussing NETs** in the Capital Markets Day webinar (between 13:34 and 18:30) that is still posted on the company's website at https://ir.volition.com/news-events/ir-calendar.

Early diagnosis of sepsis is key to patient outcomes and reduces long-term morbidity. Specifically, the risk of death increases 7.6% for each hour the appropriate antibiotic therapy is delayed. Current assessment tests, SOFA (Sequential Organ Failure Assessment used in Europe) and APACHE II (used in the U.S.), are complex and require time to process. It appears that V**olition's Nu.Q NETs test correlates well with the SOFA score**, according to an observational study by Morimont et al published in July 2022.[i]

The Nu.Q NETs assay was **granted** the **CE Mark** (Conformitè Europëenne) certification process in **Europe in late May 2022**. Volition registered the Nu.Q NETs assay (H3.1 nucleosome) 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.

The road map to commercialization was discussed. In 2022, Volition became a **member of the International Sepsis Forum**, an important organization in the sepsis field. To date, **two clinical papers** and **six posters** have been published providing clinical evidence of the efficacy of the Nu.Q NETs assay for the detection of sepsis.

Volition is **pursuing Breakthrough Device Designation (BDD)** the U.S. The company's **Carlsbad laboratory** facility is helping spearhead the sepsis development program in the U.S. Management expects to submit a request for the BDD designation during the second quarter of 2023.

Clinical studies are underway with **Diagnostic Oncology CRO** (aka DXOCRO, a contract research organization) which specializes in the commercialization of diagnostic biomarkers. VolitionRx appointed DXOCRO to develop and conduct large-scale clinical validation studies for Nu.Q NETs in August 2022. Furthermore, DXOCRO is helping lead Volition's regulatory program in the U.S. with the goal of gaining clearance, authorization or approval from the FDA. Management believes that the mandatory FDA regulatory trials could be completed by the end of 2025.



VolitionRx Capital Markets Day Presentation May 11, 2023

Nu.Q Vet - Distribution



VolitionRx Capital Markets Day Presentation May 11, 2023

IDEXX Laboratories

In mid-October 2022**,** Volition signed a **Global Supply Agreement** for the Nu.Q Vet Cancer Test with **IDEXX Laboratories**, Inc. (NASDAQ: IDXX), a market leader in pet healthcare with 80 laboratories servicing over 50,000 veterinary practices. Through the Agreement, Volition's Nu.Q Vet Cancer Test will

be offered by IDEXX as the **IDEXX Nu.Q Canine Cancer Screening Test** and the test will be processed through reference laboratories.

IDEXX Labs introduced the IDEXX Nu.Q Canine Cancer Screening Test at the Orlando Conference on January 12, 2023. **IDEXX's product launch is expected in the second half of 2023**.

Heska Corporation

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 signing (in late-March 2022) and will receive up to an additional $18 million based upon the achievement of certain milestones, namely $6.5 million on the commercial launch of the point-of-care as a screening test, $6.5 million at the first commercial sale of a monitoring test and $5 million when the work on the feline test is finalized. The Feline test is currently in the pre-analytics stage

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 was granted **non-exclusive rights to sell the Nu.Q Vet test kits through its reference laboratory network**. The payment for the kits and key components will be at pre-agreed prices, which should provide another revenue stream for VolitionRx. Through Heska, **Scil Lab** launched Nu.Q Vet test kits **in Europe** during November 2022.



The **acquisition of Heska by Mars** Inc. (announced in early-May 2023 for $1.3 billion) is expected to be a net positive since it adds Mars Petcare with an international network of over 2,500 pet hospitals (including Banfield, BluePearl, Mount Pleasant and VCA) to the network under the Global License and Supply Agreement, which should generate additional revenues for VolitionRx. The acquisition is expected to close in the second half of 2023.

SAGE Healthcare

In mid-December 2021**,** Volition signed a **Global Supply Agreement** for the Nu.Q Vet Cancer Test **with a market leader in pet healthcare**. 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. Through the Agreement, Volition provides its Nu.Q Vet Cancer Test through SAGE Healthcare and makes its reference laboratory network available for the screening test of the blood samples drawn by veterinarians.

DNAtech

DNAtech launched the Nu.Q Vet Cancer in **Portuga**l during late-November 2022. DNAtech has three laboratories located in the Lisbon, Porto and Algarve regions of Portugal and services over 2,300 customers.



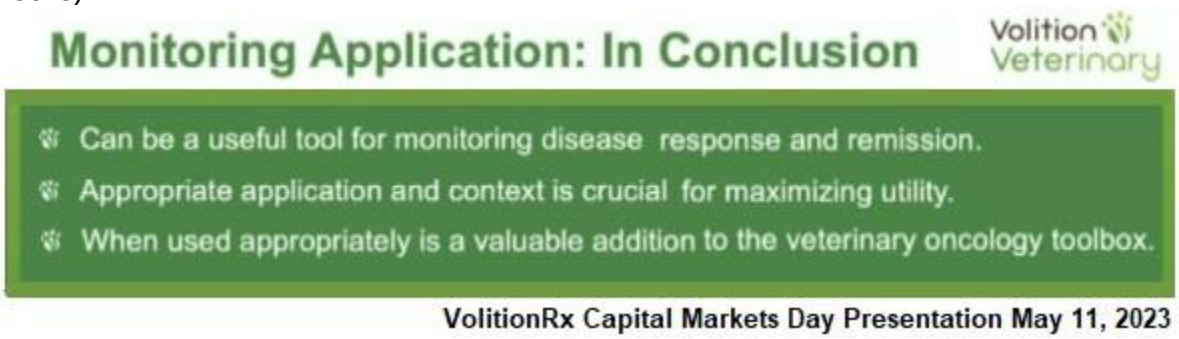


Nu.Q Vet – Clinical Paper for Monitoring

On May 10, 2023, a **clinical paper** on utilizing nucleosome concentrations as a **tool for monitoring treatment response and remission status** of canines with hematopoietic cancers. Entitled "**Monitoring plasma nucleosome concentrations to measure of disease response and progression in dogs with hematopoietic malignancies**", the study was led by Dr. Heather Wilson-Robles, Chief Medical Officer at Volition Veterinary. The paper can be read at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0281796

The study evaluated 40 dogs with lymphoma, acute myelogenous leukemia and multiple myeloma. The study "found that plasma nucleosome concentrations were significantly higher at diagnosis and progressive disease than they were when dogs were in remission. The study also showed that nucleosome concentrations nearly always returned to the low range during treatment and are associated with clinical remission."

As a result of this paper, the Nu.Q Vet Cancer Detection Test has a **new indication** for monitoring and now can be used as a **Nu.Q Vet Cancer Monitoring Test** for canine **lymphoma** management. Dr. Wilson-Robles recommends that the Nu.Q Vet Cancer Test be used at diagnosis, once per cycle during treatment (at least four times), at remission and every following check-up (normally every 4-to-6 weeks).

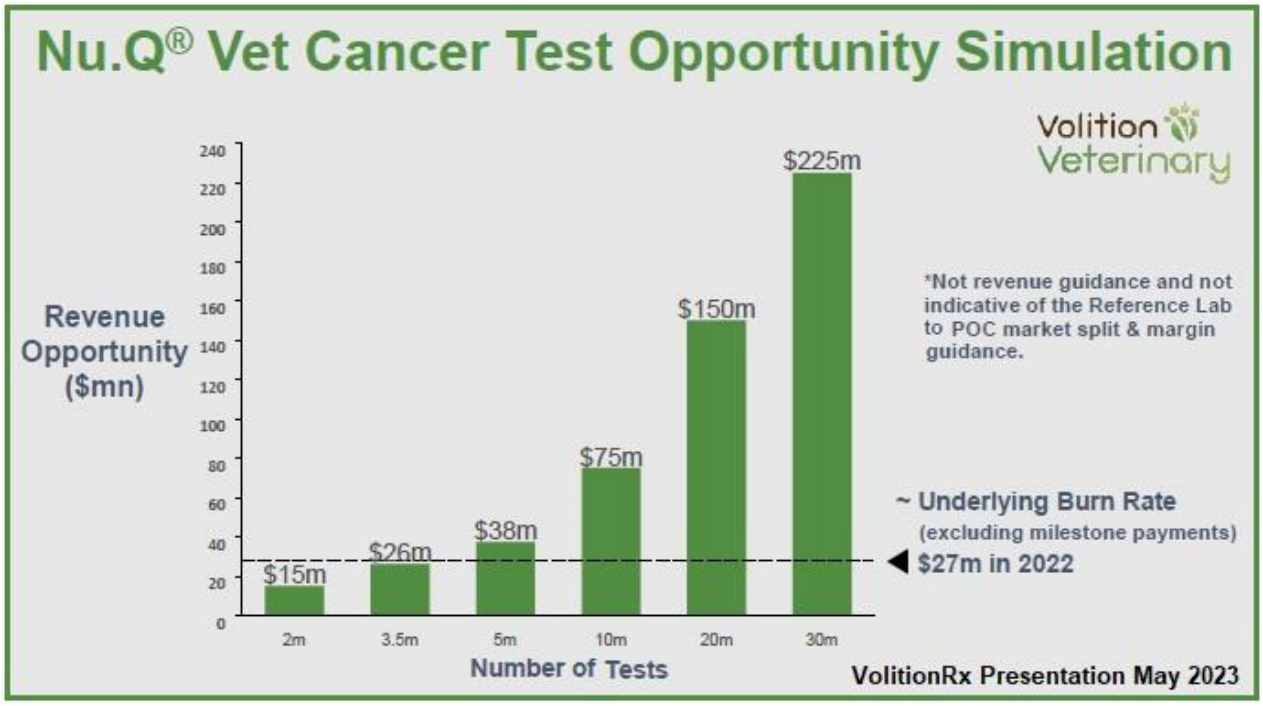


Nu.Q Vet Cancer Detection Test

Key opinion leader, Dr. Sue Ettinger, recommended that all dogs should be tested with the Nu.Q Vet Cancer Test over age of seven (7) at their **annual wellness check-up**, while **high-risk breeds** (shown in the slide below) should be tested **around the age three or four**. The test should be administered on healthy, fasted canines.



Management has presented an opportunity simulation for the Nu.Q Vet Test to illustrate the **revenue potential** at certain levels of tests being administered. Based on the simulation, between 3.7 million and 4.0 million tests annually would cover the company's level of cash burn.



IP Portfolio

VolitionRx has a substantial worldwide IP portfolio with **96 patents** and **120 patent applications pending** as of May 11, 2023.

RECENT FINANCING

On June 5, 2023, VolitionRx announced the details of another underwritten public offering pursuant to a shelf registration statement initially filed in September 2021. The **offering of 13,000,000 shares** was priced at $1.75 per share. **Gross proceeds were approximately $16.5 million**. The net proceeds will be used for R&D, clinical studies and product commercialization as well as for working capital purposes, including potential strategic acquisitions. Freedom Capital Markets acted as the book-running manager and Bancroft
Capital acted as co-manager.

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 for diagnosis and monitoring 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[ii]). 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%[iii]). 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%.[iv] 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)

The company's **principal research & 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 serves 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.

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 **$4.30 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, +10.6% in 2021 and 7.6% in 2022 as equity financings have helped fund the company's research & development costs and general corporate expenses. Thus far in 2023, shares outstanding increased 31.5%. 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)	2019	2020	2021	2022	1Q 2023
Period ending	12/31/2019	12/31/2020	12/31/2021	12/31/2022	3/31/2023
ASSETS					
Cash and cash equivalents	16,966,168	19,444,737	20,581,313	10,867,050	10,010,878
Accounts receivable	-	7,118	12,510	72,609	118,592
Prepaid expenses	267,518	303,178	598,367	784,920	1,111,318
Other current assets	322,593	576,660	786,642	447,566	716,910
Total Current Assets	**17,556,279**	**20,331,693**	**21,978,832**	**12,172,145**	**11,957,698**
Property, plant and equipment	2,981,225	5,171,134	4,911,077	5,393,012	5,401,896
Operating lease right-of-use assets	381,483	326,085	383,551	619,392	593,108
Intangible assets	372,305	321,641	216,876	110,505	90,831
TOTAL ASSETS	**21,291,292**	**26,150,553**	**27,490,336**	**18,295,054**	**18,043,533**
Accounts payable	627,253	1,539,547	1,542,457	3,043,008	2,989,460
Accrued liabilities	2,168,588	3,491,740	3,841,013	2,872,247	2,719,182
Deferred revenue	-	-	-	10,000,000	10,000,000
Management and directors' fees payable	21,979	55,174	71,303	71,119	80,138
Current portion of long-term debt	647,569	841,319	797,855	1,066,700	1,121,069
Current portion of financing lease liabilities	97,946	59,930	48,958	46,014	46,917
Current portion of operating lease liabilities	257,244	179,624	171,166	245,163	238,764
Deferred grant income	-	-	-	-	-
Current portion of grant repayable	39,295	69,218	43,100	41,836	42,382
Total Current Liabilities	**3,859,874**	**6,236,552**	**6,515,852**	**17,386,087**	**17,237,912**
Long-term debt	2,195,278	2,606,885	2,270,767	2,779,240	2,549,116
Financing lease liabilities	607,708	601,967	511,086	436,132	429,977
Operating lease liabilities	131,875	151,828	217,305	400,091	381,722
Grant repayable	297,991	259,603	253,221	420,466	425,951
Non-Current Liabilities	**3,232,852**	**3,620,283**	**3,252,379**	**4,035,929**	**3,786,766**
TOTAL LIABILITIES	**7,092,726**	**9,856,835**	**9,768,231**	**21,422,016**	**21,024,678**
SHAREHOLDERS' EQUITY					
Common Stock	41,125	48,607	53,772	57,873	63,112
Additional paid-in capital	103,853,627	126,526,239	154,730,938	164,397,468	173,467,433
Accumulated other comprehensive income	125,670	(59,978)	148,326	227,097	170,619
Accumulated deficit	(89,821,856)	(110,173,971)	(136,988,636)	(167,257,429)	(176,036,977)
Total VolitionRx Stockholders' Equity	**14,198,566**	**16,340,897**	**17,944,400**	**(2,574,991)**	**(2,335,813)**
Non-controlling interest	-	(47,179)	(222,295)	(551,971)	(645,332)
Total Stockholders' Equity	**14,198,566**	**16,293,718**	**17,722,105**	**(3,126,962)**	**(2,981,145)**
TOTAL LIABILITIES & STOCKHOLDERS' EQUIT	**21,291,292**	**26,150,553**	**27,490,336**	**18,295,054**	**18,043,533**
Shares outstanding	41,125,303	48,607,017	53,772,261	57,873,379	63,111,766

PROJECTED ANNUAL INCOME STATEMENTS

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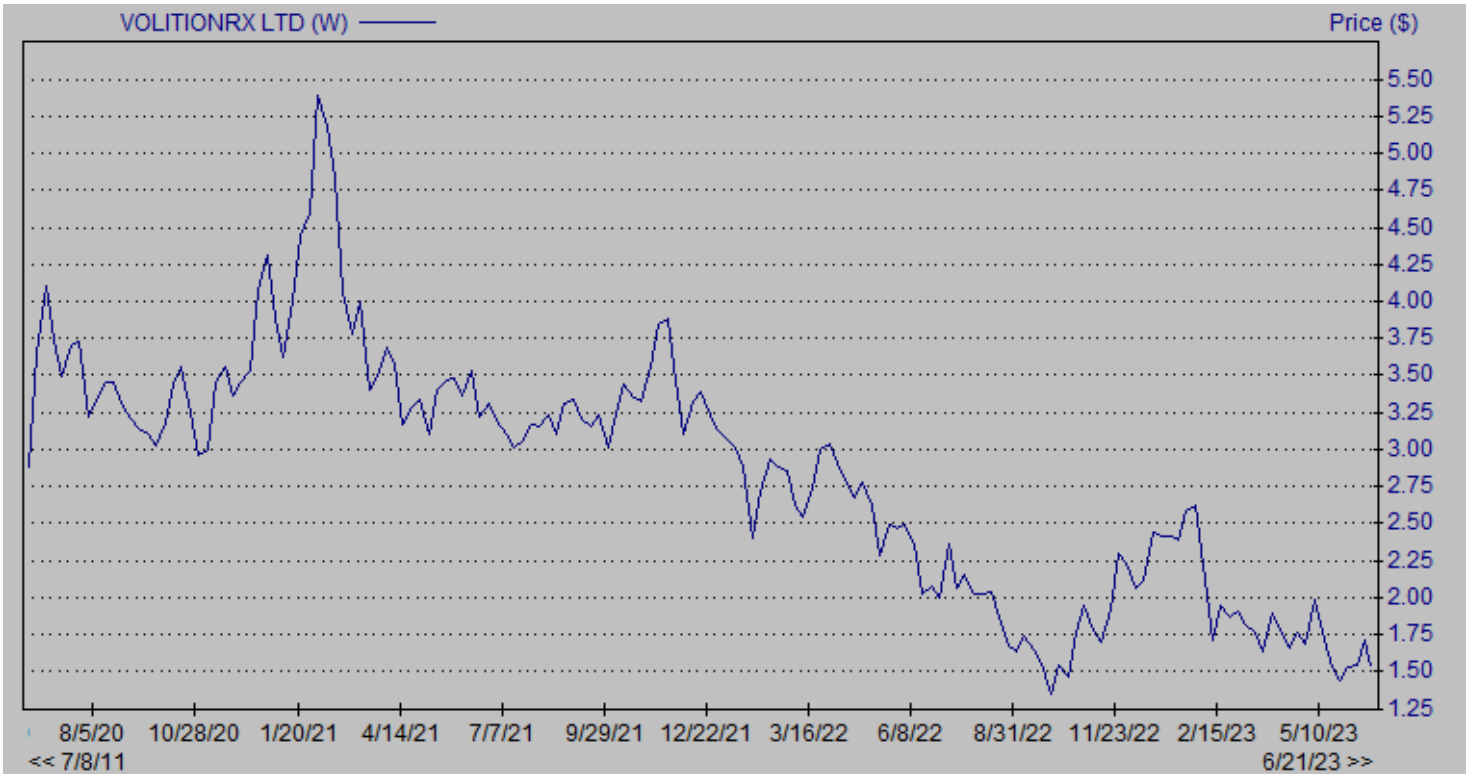
QUARTERLY INCOME STATEMENTS

VolitionRx Limited						
Income Statement (in $US except share and per share data)	**2022 12/31/2022**	**1Q 2023 3/31/2023**	**2Q E 2023 6/30/2023**	**3Q E 2023 9/30/2023**	**4Q E 2023 12/31/2023**	**Estimate 2023 12/31/2023**
Product	210,993	144,452	270,000	530,000	1,200,000	2,144,452
Agreement Fee	0	0	0	0	0	0
Service (Contract lab services)	92,488	5,356	15,000	15,000	25,000	60,356
Royalty (Research kits)	2,911	0	0	0	0	0
Total Revenues	**306,392**	**149,808**	**285,000**	**545,000**	**1,225,000**	**2,204,808**
Expenses						
Research and development	14,572,532	4,905,678	4,481,077	5,107,181	5,418,904	19,912,840
General and administrative	10,937,686	2,581,703	3,100,000	2,750,000	2,500,000	10,931,703
Sales and marketing	6,576,246	1,707,457	1,800,000	1,500,000	1,500,000	6,507,457
Total Operating Expenses	**32,086,464**	**9,194,838**	**9,381,077**	**9,357,181**	**9,418,904**	**37,352,000**
Loss Before Other Income	**(31,780,072)**	**(9,045,030)**	**(9,096,077)**	**(8,812,181)**	**(8,193,904)**	**(35,147,192)**
Grant income	1,229,425	165,795	310,000	310,000	310,000	1,229,425
Interest income	125,265	57,648	100,000	75,000	50,000	125,265
Interest (expense)	(173,087)	(51,322)	(45,322)	(39,322)	(33,322)	(173,087)
Gain (loss) disposal of fixed assets	0	0	0	0	0	0
Other income (expense)	0	0	0	0	0	0
Total Other Income (Expenses)	**1,181,603**	**172,121**	**364,678**	**345,678**	**326,678**	**1,181,603**
Net Gain (Loss)	**(30,598,469)**	**(8,872,909)**	**(8,731,399)**	**(8,466,503)**	**(7,867,226)**	**(33,965,589)**
Net Gain (Loss) Non-Controlling Int.	(329,676)	(93,361)	(94,299)	(91,438)	(84,966)	(329,676)
Net Gain (Loss) - VNRX Stockholders	**(30,268,793)**	**(8,779,548)**	**(8,637,100)**	**(8,375,065)**	**(7,782,260)**	**(33,635,913)**
Basic and diluted loss per share	**(0.55)**	**(0.15)**	**(0.13)**	**(0.11)**	**(0.10)**	**(0.48)**
Wgted. Avg. Shares Out. - diluted	55,350,401	60,176,975	67,400,000	76,111,766	76,361,766	70,012,627

HISTORICAL STOCK PRICE



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