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Zacks Small-Cap Research

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VolitionRx Ltd (NYSE: VNRX)

Additional Launches of Nu.Q Vet Cancer Screening Test Announced; 4.945 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 $5.75 per share.

OUTLOOK

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

Heska's **European launch** and **IDEXX's international launches** are anticipated.

$6.5 million milestone payment from Heska expected during first half of 2023

Current Price (02/24/23)	$1.88
Valuation	**$5.75**

SUMMARY DATA

52-Week High	**$4.14**
52-Week Low	**$1.31**
One-Year Return (%)	**-28.79**
Beta	**1.73**
Average Daily Volume (shrs.)	**194,588**
Shares Outstanding (million)	**62.4**
Market Capitalization ($mil.)	**$117.4**
Short Interest Ratio (days)	**9.8**
Institutional Ownership (%)	**16.6**
Insider Ownership (%)	**12.3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/M**
P/E using 2022 Estimate	**N/M**
P/E using 2023 Estimate	**N/M**

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

ZACKS ESTIMATES

Revenue
(in thousands of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0.5 A	5.2 A	0.6 A	7.1 A	13.4 A
2021	25.5 A	24.8 A	25.5 A	14.2 A	90.9 A
2022	114 A	40 A	33 A	55 E	239 E
2023					500 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.14 A	-$0.12 A	-$0.09 A	-$0.11 A	-$0.45 A
2021	-$0.12 A	-$0.10 A	-$0.13 A	-$0.15 A	-$0.51 A
2022	-$0.14 A	-$0.14 A	-$0.14 A	-$0.15 E	-$0.57 E
2023					-$0.61 E

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

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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 **commercial strategy** involves targeting several specific markets. The most advanced commercialization effort is with the **Nu.Q Vet** blood assay as a **cancer detection test for canines**. The company is in the process of expanding the test's indication to cancer monitoring for canines. Furthermore, research has begun to expand those indications to felines.

RECENT EVENTS IN THE COMMERCIALIZATION OF THE Nu.Q Vet CANCER TEST

Volition is expanding the distribution network for the commercialization of its **Nu.Q Vet** Cancer Test. Thus far, **several supply agreements have been announced** and more are expected:

- **non-exclusive supply agreement** with **SAGE Healthcare for Asia** (mid-December 2021)
- **point-of-care test** supply agreement **with Heska Corp.** (March 29, 2022),
- global supply agreement with **IDEXX Labs** through its reference lab network (October 2022)

Launches of Nu.Q Vet Cancer Test

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.

On November 3rd, **Heska launched the reference lab-version** Nu.Q Vet Cancer Screening Test **across the U.S**. Blood samples will be processed at Heska's Veterinary Diagnostic Laboratory. The launch advances the path toward the receipt of the $18 million in milestone payments that are part of the Supply Agreement with Heska.

In December 2022, **DNAtech launched** the Nu.Q® Vet Cancer Test in Portugal. DNAtech has three laboratories located in the Lisbon, Porto and Algarve regions of Portugal and services over 2300 customers.

On January 12, 2023, Volition announced the **launch** of the Nu.Q Vet Cancer Test **through the IDEXX Laboratories' reference laboratory network in the U.S**.

Then on February 16th, Volition announces that **Heska's point-of-care version** of the Nu.Q Vet Cancer Test is **available for pre-order** by veterinarians. The Nu.Q® test was showcased at the 2023 Western Veterinary Conference held in Las Vegas. The test can be processed on Heska's point-of-care platform, the Element i+ Immunodiagnostic. The price point is under $50.

These product launches are major milestones in the commercialization of the Nu.Q Vet test, which should accelerate the growth of the revenue stream from this product in 2023.

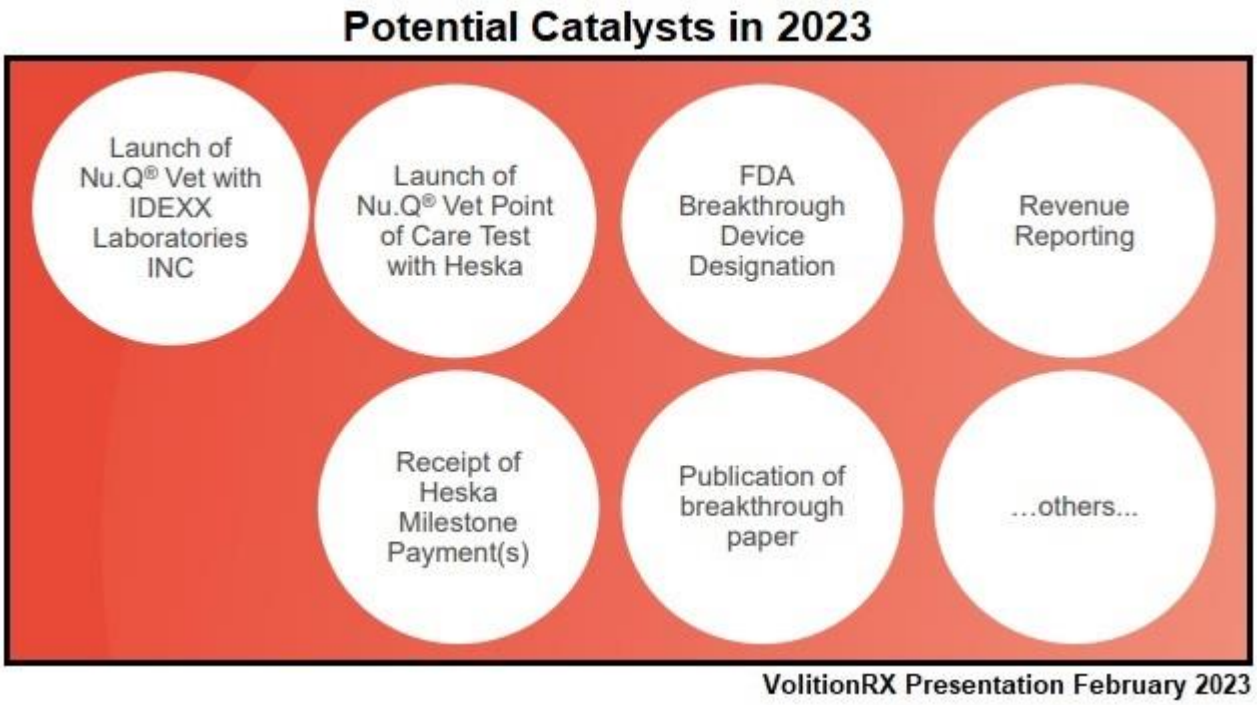


VolitionRX Presentation February 2023

Anticipated Launches of Nu.Q Vet Cancer Test

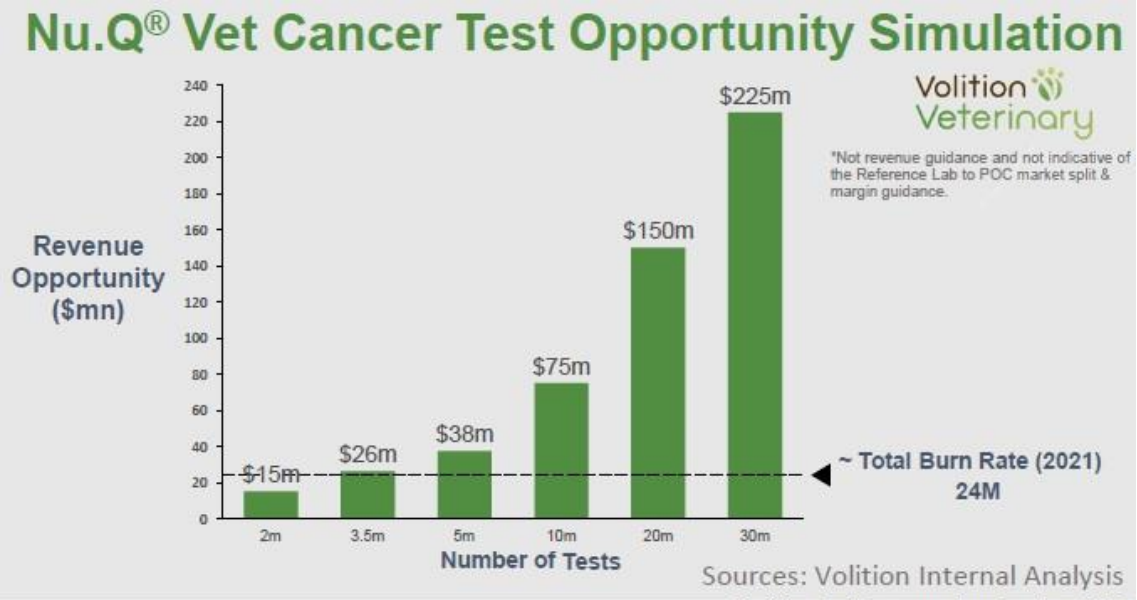
During 2023, probably in the first half, Heska is expected to launch of the **point-of-care version**. This event will **trigger a milestone payment of $6.5 million to VolitionRx**.

Also, it is anticipated that **IDEXX Laboratories** will **launch** of the Nu.Q Vet Cancer Test **internationally**.



VolitionRX Presentation February 2023

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



VolitionRx Presentation October 2022

DETAILS OF SELECT SUPPLY AGREEMENTS

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**. Through the Agreement, Volition will provide its Nu.Q Vet Cancer Test and make its reference laboratory network available for the screening test of the blood samples drawn by veterinarians. Further details will be announced at the time of the official launch.

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) and will receive up to an additional $18 million based upon the achievement of certain milestones. 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.

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). Through the Agreement, Volition's Nu.Q Vet Cancer Test will

be offered by IDEXX as the **IDEXX Nu.Q Canine Cancer Screening Test**. IDEXX is a market leader in pet healthcare with 80 labs servicing over 50,000 veterinary practices.

FINANCING

On February 17th 2023, VolitionRx announces the details of an underwritten public offering pursuant to a shelf registration statement initially filed in September 2021. The **offering of 4,945,000 shares** , which includes full exercise of the underwriter's overallotment, was priced at $1.75 per share. **Gross proceeds were approximately $8.7 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.

INSTITUTIONAL OWNERSHIP UPDATE

On February 14th 2023, Lagoda Investment Management, L.P. filed Form 13-D reporting a beneficial ownership of 3,755,045 shares or 6.53% of the shares then outstanding.

OVERVIEW

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

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

Management's Conceptual Business Development Model

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

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

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

VolitionRx has undertaken the task to address a global unmet need - the scarcity of robust, low-cost screens for cancer. For example, the predominant screens for **lung cancer** are a chest x-ray and/or CT scan, both of which subject patients to radiation. If a suspected area of cancer is detected, a biopsy follows, which has the associated risks of pneumonia, blood clots, infection, adverse anesthesia complications, pleural effusion or pneumothorax (i.e. a collapsed lung, which occurs in 15% of lung biopsy patients[i]). For **colorectal cancer**, a patient is advised to undergo a colonoscopy, which is invasive and can cause an infection, perforation (incidence of 1.96 per 1,000 procedures), bleeding and, in rare cases, death (probability of 0.01%[ii]). Therefore, many patients are reticent to undergo a colonoscopy, and some forgo the test altogether. For those who choose to avoid a colonoscopy and are later diagnosed with stage IV colorectal cancer, little more than 5% survive for five years. Conversely, those diagnosed with stage I bowel cancer (through early detection) have a five-year survival rate of 89.8%.[iii] An early diagnosis of both lung and colorectal cancer dramatically improves a patient's outcome. A low-risk, low-cost, blood-based test would aid in realizing an earlier diagnosis for many patients.

R&D Center (Isnes, Belgium)



VolitionRx Presentation May 13, 2020

The company's **principal research & 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.

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 **$5.75 per share**.

RISKS

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

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

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

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

BALANCE SHEET

VolitionRx Limited					
(in $US except share data)	2018	2019	2020	2021	3Q 2022
Period ending	12/31/2018	12/31/2019	12/31/2020	12/31/2021	9/30/2022
ASSETS					
Cash and cash equivalents	13,427,222	16,966,168	19,444,737	20,581,313	16,416,069
Accounts receivable	-	-	7,118	12,510	5,492
Prepaid expenses	245,441	267,518	303,178	598,367	825,748
Other current assets	229,755	322,593	576,660	786,642	426,228
Total Current Assets	**13,902,418**	**17,556,279**	**20,331,693**	**21,978,832**	**17,673,537**
Property, plant and equipment	3,119,643	2,981,225	5,171,134	4,911,077	4,880,663
Operating lease right-of-use assets	-	381,483	326,085	383,551	657,557
Intangible assets	466,905	372,305	321,641	216,876	129,600
TOTAL ASSETS	**17,488,966**	**21,291,292**	**26,150,553**	**27,490,336**	**23,341,357**
Accounts payable	807,162	627,253	1,539,547	1,542,457	2,467,672
Accrued liabilities	923,034	2,168,588	3,491,740	3,841,013	3,069,288
Deferred revenue	-	-	-	-	10,000,000
Management and directors' fees payable	1,200	21,979	55,174	71,303	71,642
Current portion of long-term debt	416,553	647,569	841,319	797,855	1,064,741
Current portion of financing lease liabilities	145,150	97,946	59,930	48,958	41,693
Current portion of operating lease liabilities	-	257,244	179,624	171,166	232,161
Deferred grant income	-	-	-	-	-
Current portion of grant repayable	40,094	39,295	69,218	43,100	30,908
Total Current Liabilities	**2,333,193**	**3,859,874**	**6,236,552**	**6,515,852**	**16,978,105**
Long-term debt	1,984,262	2,195,278	2,606,885	2,270,767	2,275,045
Financing lease liabilities	720,013	607,708	601,967	511,086	408,344
Operating lease liabilities	-	131,875	151,828	217,305	449,326
Grant repayable	311,042	297,991	259,603	253,221	390,709
Non-Current Liabilities	**3,015,317**	**3,232,852**	**3,620,283**	**3,252,379**	**3,523,424**
TOTAL LIABILITIES	**5,348,510**	**7,092,726**	**9,856,835**	**9,768,231**	**20,501,529**
SHAREHOLDERS' EQUITY					
Common Stock	35,335	41,125	48,607	53,772	57,496
Additional paid-in capital	85,604,271	103,853,627	126,526,239	154,730,938	162,939,998
Accumulated other comprehensive income	223,651	125,670	(59,978)	148,326	315,546
Accumulated deficit	(73,722,801)	(89,821,856)	(110,173,971)	(136,988,636)	(160,015,333)
Total VolitionRx Stockholders' Equity	**12,140,456**	**14,198,566**	**16,340,897**	**17,944,400**	**3,297,707**
Non-controlling interest	-	-	(47,179)	(222,295)	(457,879)
Total Stockholders' Equity	**12,140,456**	**14,198,566**	**16,293,718**	**17,722,105**	**2,839,828**
TOTAL LIABILITIES & STOCKHOLDERS' EQUIT	**17,488,966**	**21,291,292**	**26,150,553**	**27,490,336**	**23,341,357**
Shares outstanding	35,335,378	41,125,303	48,607,017	53,223,761	53,790,261

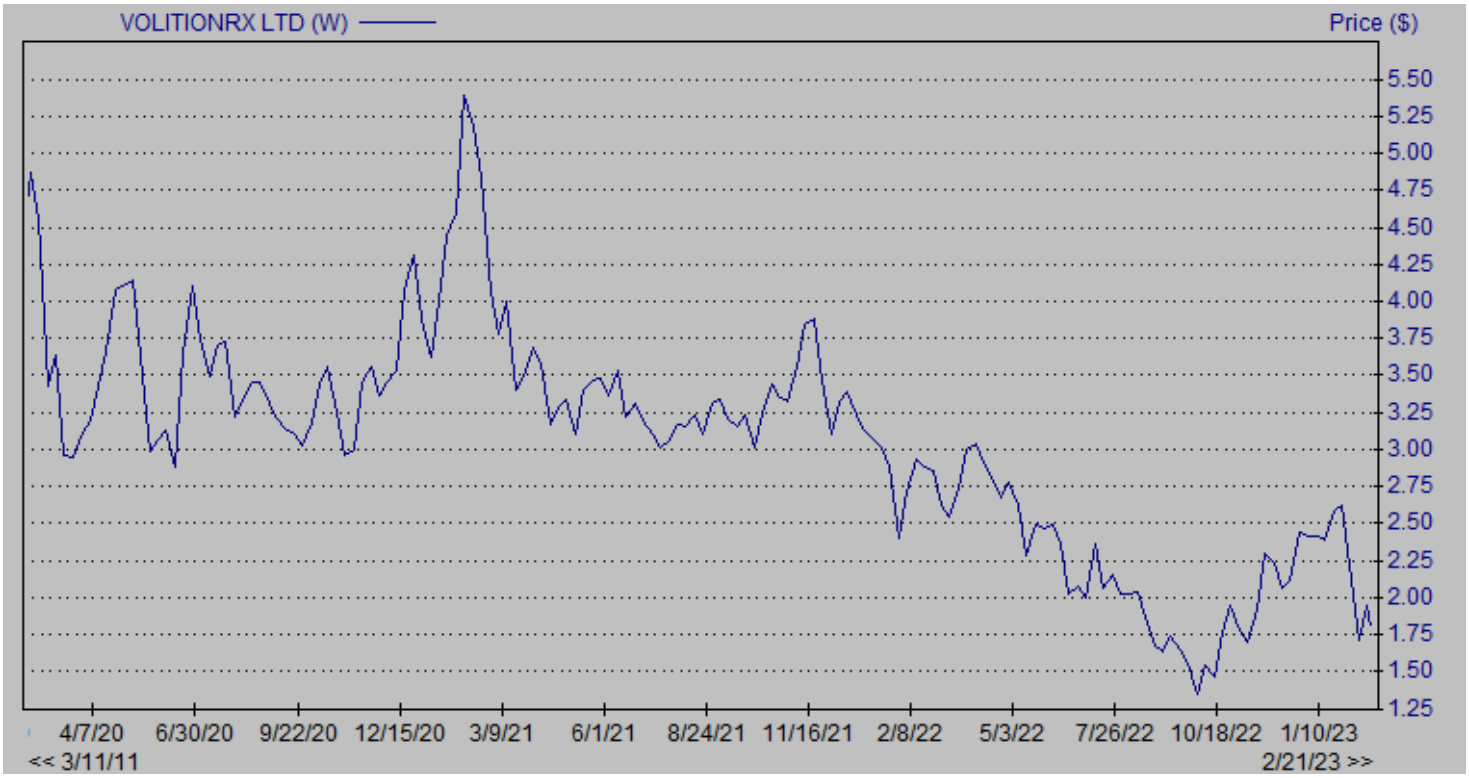
PROJECTED ANNUAL INCOME STATEMENTS

VolitionRx Limited					
Income Statement	2018	2019	2020	2021	2022 Est.
(in $US, except share and per share data)	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
Product	-	-	11,321	90,035	148,585
Agreement Fee					0
Service (Contract lab services)	-	16,204	0	0	90,181
Royalty (Research kits)	-	892	2,112	0	0
Total Revenues	**0**	**17,096**	**13,433**	**90,035**	**238,766**
Expenses					
Research and development	10,906,871	10,363,253	14,533,862	15,541,889	14,456,533
General and administrative	5,821,072	4,731,054	5,654,018	8,751,392	11,297,292
Sales and marketing	1,169,756	965,713	1,073,368	4,129,833	6,544,947
Total Operating Expenses	**17,897,699**	**16,060,020**	**21,261,248**	**28,423,114**	**32,298,773**
Loss Before Other Income	**(17,897,699)**	**(16,042,924)**	**(21,247,815)**	**(28,333,079)**	**(32,060,007)**
Grant income	-	155,031	635,513	1,522,533	564,879
Interest income	-	112,367	49,495	2,734	58,508
Interest (expense)	(110,924)	(126,572)	(129,799)	(155,803)	(154,690)
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**	**468,697**
Net Gain (Loss)	**(18,008,623)**	**(16,099,055)**	**(20,399,294)**	**(26,989,781)**	**(31,591,310)**
Net Gain (Loss) Non-Controlling Int.	-	-	(47,179)	(175,116)	(150,996)
Net Gain (Loss) - VNRX Stockholders	**(18,008,623)**	**(16,099,055)**	**(20,352,115)**	**(26,814,665)**	**(31,440,314)**
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	55,056,439

QUARTERLY INCOME STATEMENTS

VolitionRx Limited						
Income Statement (in $US except share and per share data)	**2021 12/31/2020**	**1Q 2022 3/31/2021**	**2Q 2022 6/30/2021**	**3Q 2022 9/30/2021**	**4Q E 2022 12/31/2021**	**Estimate 2022 12/31/2021**
Product	90,035	53,957	29,706	19,922	45,000	148,585
Agreement Fee	-	0	0	0	0	0
Service (Contract lab services)	0	60,254	10,046	9,881	10,000	90,181
Royalty (Research kits)	0	0	0	2,911	0	0
Total Revenues	**90,035**	**114,211**	**39,752**	**32,714**	**55,000**	**238,766**
Expenses						
Research and development	15,541,889	3,590,053	3,279,323	3,737,516	3,849,641	14,456,533
General and administrative	8,751,392	2,602,152	3,085,840	2,763,202	2,846,098	11,297,292
Sales and marketing	4,129,833	1,598,983	1,774,064	1,524,952	1,646,948	6,544,947
Total Operating Expenses	**28,423,114**	**7,791,188**	**8,139,227**	**8,025,670**	**8,342,688**	**32,298,773**
Loss Before Other Income	**(28,333,079)**	**(7,676,977)**	**(8,099,475)**	**(7,992,956)**	**(8,287,688)**	**(32,060,007)**
Grant income	1,522,533	0	393,440	171,439		564,879
Interest income	2,734	2	11,161	46,945	400	58,508
Interest (expense)	(155,803)	(41,032)	(37,129)	(37,699)	(38,830)	(154,690)
Gain (loss) disposal of fixed assets	(26,166)	0	0	0	0	0
Other income (expense)	0	0	0	0	0	0
Total Other Income (Expenses)	**1,343,298**	**(41,030)**	**367,472**	**180,685**	**(38,430)**	**468,697**
Net Gain (Loss)	**(26,989,781)**	**(7,718,007)**	**(7,732,003)**	**(7,812,271)**	**(8,326,118)**	**(31,591,310)**
Net Gain (Loss) Non-Controlling Int.	(175,116)	(83,977)	(82,302)	69,305	(54,022)	(150,996)
Net Gain (Loss) - VNRX Stockholders	**(26,814,665)**	**(7,634,030)**	**(7,649,701)**	**(7,881,576)**	**(8,272,096)**	**(31,440,314)**
Basic and diluted loss per share	**(0.51)**	**(0.14)**	**(0.14)**	**(0.14)**	**(0.15)**	**(0.57)**
Wgted. Avg. Shares Out. - diluted	52,655,885	53,775,096	53,810,500	56,120,079	56,520,079	55,056,439

HISTORICAL STOCK PRICE



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