

# VolitionRx Limited Announces Third Quarter 2017 Financial Results and Business Update

ISNES, Belgium, Nov. 9, 2017 /PRNewswire/ -- VolitionRx Limited (NYSE American: VNRX) today announced financial results and a business update for the third quarter ended September 30, 2017. Volition management will host a conference call tomorrow, November 10, at 8:30 a.m. U.S. Eastern Time to discuss these results. Conference call details may be found below.

Mr. Cameron Reynolds, President and Chief Executive Officer of Volition, said, "We have made fantastic progress this quarter, moving our clinical product development strongly forward in Asia, Europe and the U.S, and broadening our potential revenue base with our recently announced research kit sales. We have further expanded our talented scientific team, with four new hires to the R&D team, financially supported by the local government in Belgium." Mr. Reynolds added, "We continue to announce large trials at very affordable costs in our efforts to gain worldwide adoption of our products. We look forward to achieving our upcoming clinical and commercial milestones, while continuing to keep close control on our cash burn, which has remained relatively stable."

# Third Quarter 2017 and Recent Company Highlights

#### Clinical

- As the cornerstone of our frontline screening colorectal cancer test for the all-important U.S. market, we entered into an agreement to participate in a large, multi-center study with the Great Lakes New England Clinical Validation Center, funded by the U.S. National Cancer Institute's Early Detection Research Network.
  - The objective is to validate Volition's Nu.Q™ Colorectal Cancer Screening Test in a large, asymptomatic population for U.S. regulatory purposes.
  - The study provides approximately 13,500 asymptomatic screening samples of people aged 50 or over who have not previously undergone screening or a diagnostic colonoscopy.
  - The study will come at a cost of no more than \$3 million, paid in equal, quarterly installments.

## Intellectual Property

- We secured four additional patents, in the U.S., Europe, Mexico and Australia, further solidifying Volition's intellectual property portfolio worldwide.
  - The patents are complementary to those previously granted. Volition now has 5 granted patents in the U.S. and 8 more patents in other territories.

## Operational

- In line with our goals to best utilize our Nucleosomics® platform and to broaden our revenue base, we announced the initial order of a bespoke Nu.Q<sup>TM</sup> clinical research use only kit from a large multi-national pharmaceutical company together with plans to launch a range of Nucleosomics® clinical research use only kits in the first half of 2018.
  - The kits based on our proprietary Nucleosomics® technology are expected to:
    - allow researchers to explore patterns of epigenetic modifications in circulating nucleosomes across a broad range of clinical applications including cancers, inflammatory and infectious diseases. The kits can be used for many purposes, for example as an aid to drug development and treatment selection.
    - represent the first revenue from the Nu.Q<sup>TM</sup> platform and potentially provide an additional licensing revenue stream beyond the commercialization of our blood-based cancer tests on the same platform of assays.
- We commenced a project to investigate the use of Nucleosomics® to purify or enrich nucleosomes from cancer. This aims to provide purified circulating tumor DNA to help address the main technology barrier in this emergent field of cancer diagnostics.
- We were awarded \$1.5 million in non-dilutive funding from SOFINEX and the Walloon Region of Belgium, bringing the total amount of non-dilutive funding from various agencies in the region to nearly \$2.5 million

## Third Quarter 2017 and Other Financial Results

For the three months ended September 30, 2017, Volition reported a net loss of \$3.89 million, or \$0.15 per share. This compares to a net loss of \$3.48 million, or \$0.15 per share in the third guarter of 2016.

Cash and cash equivalents as of September 30, 2017 totaled \$13.84 million, compared with \$12.53 million as of September 30, 2016.

# **Upcoming Milestones**

Volition is targeting several important clinical and commercial milestones, including:

- Selection of the panel for our frontline Nu.Q<sup>TM</sup> Colorectal Cancer Screening Test by the end of 2017. This panel will be subject to validation in a 4,300-subject trial in the first quarter of 2018 followed by a more than 10,000 subject cohort in second quarter of 2018. It is expected that the product will have CE marking by the third quarter of 2018, which would allow the sale of the product in all 28 European Union countries (where there is a total screening market of over 150 million persons). Regulatory approval will follow in Asia in early 2019.
- In line with our strategy to launch colorectal cancer products worldwide through working with world-class collaborators on large, cost effective trials, we hope to announce our clinical trial program in Asia.
- Completion of the Logistics and Pathway design study currently underway in Denmark.
- Launch of the Total Nucleosome Assay Research Use Only kit with an extended range in the first quarter of 2018, with increased revenue expected commencing in the second quarter of 2018.

- Update on our progress utilizing Nucleosomics<sup>®</sup> to purify or enrich nucleosomes of tumor origin.
- Obtaining additional non-dilutive funding.

## **Conference Call**

Volition will host a conference call tomorrow, November 10, at 8:30 a.m. U.S. Eastern Time, to discuss its financial and operating results for the third quarter of 2017, and to provide an update on recent developments. To participate in the call, please dial 1-877-407-9716 (toll-free) in the U.S., 0-800-756-3429 (toll-free) in the U.K., and 1-201-493-6779 (toll) internationally. A live audio webcast of the conference call will also be available via link from the investor relations page of Volition's corporate website at <a href="http://ir.volitionrx.com/">http://ir.volitionrx.com/</a>. The conference ID is 13673016.

The call will be hosted by Cameron Reynolds, President and Chief Executive Officer, along with David Vanston, Chief Financial Officer and Scott Powell, Executive Vice President.

## **About Volition**

Volition is a multi-national life sciences company developing simple, easy to use blood-based cancer tests to accurately diagnose a range of cancers. The tests are based on the science of Nucleosomics<sup>®</sup>, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid - an indication that disease is present.

As cancer screening programs become more widespread, Volition's products aim to help to diagnose a range of cancers quickly, simply, accurately and cost effectively. Early diagnosis has the potential to not only prolong the life of patients, but also to improve their quality of life.

Volition's research and development activities are currently centered in Belgium, with additional offices in London, Texas and Singapore, as the company focuses on bringing its diagnostic products to market first in Europe, then in the U.S. and ultimately, worldwide.

For more information about Volition, visit Volition's website <a href="http://www.volitionrx.com">http://www.volitionrx.com</a>) or connect with us via:

Twitter: https://twitter.com/volitionrx

LinkedIn: <a href="https://www.linkedin.com/company/volitionrx">https://www.linkedin.com/company/volitionrx</a>
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### **Safe Harbor Statement**

Statements in this press release may be "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. Words such as "expects," "anticipates," "intends," "plans," "aims," "targets," "believes," "seeks," "estimates," "optimizing," "potential," "goal," "suggests," "could," "would," "should," "may," "will" and similar expressions identify forward-looking statements. These forward-looking statements relate to the effectiveness of Volition's bodilyfluid-based diagnostic tests as well as Volition's ability to develop and successfully commercialize such test platforms for early detection of cancer. Volition's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if Volition fails to develop and commercialize diagnostic products, it may be unable to execute its plan of operations. Other risks and uncertainties include Volition's failure to obtain necessary regulatory clearances or approvals to distribute and market future products in the clinical IVD market; a failure by the marketplace to accept the products in Volition's development pipeline or any other diagnostic products Volition might develop; Volition will face fierce competition and Volition's intended products may become obsolete due to the highly competitive nature of the diagnostics market and its rapid technological change; and other risks identified in Volition's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that Volition files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about Volition's business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Forward-looking statements are made as of the date of this release, and, except as required by law, Volition does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

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