VolitionRx

Vetting the pet health opportunity

While pets are increasingly being 'humanized', their healthcare has lagged advancements seen on the human side. With the COVID-19 pandemic accelerating the trend of pet ownership, demand for improved care in a market with limited alternatives has triggered the need for newer-generation pet diagnostics. VolitionRx, a diagnostics company focused on sepsis and cancer detection, has pioneered a low-cost, quick-turnaround, cancer screening and monitoring tool for companion animals (Nu.Q Vet), an adaption of its core nucleosome quantification (Nu.Q) platform on the human side. With supply and distribution deals with leading veterinary diagnostics players IDEXX and Heska already signed, Nu.Q Vet has the building blocks in place to evolve into a potential disrupter in the space.

A novel diagnostic tool spanning multiple indications

VolitionRx utilizes its proprietary Nu.Q technology for blood-based detection of different cancers (in both humans and companion animals) and sepsis. The platform uses fragments of chromosomes (called nucleosomes) released into the bloodstream following cell death (such as in the case of cancer) as biomarkers to identify diseases. This non-invasive method of detection (versus tissue biopsies), based on the traditional enzyme-linked immunosorbent assay (ELISA) test, can be easily integrated into existing lab protocols at a low cost and offers shorter turn-around times, a distinct competitive advantage over other technology platforms. VolitionRx has built a strong patent portfolio around the Nu.Q assay, with c 90 approved patents and a further c 128 patent applications pending, providing significant market protection.

No pet(ty) business

While VolitionRx is working towards fully defining the clinical utility and intended use of the assay in humans, the veterinary opportunity has been quicker to monetize, with a soft launch in the US in December 2020 and in Singapore in April 2022 (through partner SAGE Healthcare). Animal health remains a commercially lucrative area courtesy of a relatively relaxed regulatory environment (510(k) pre-market approval is not required), a large market (50% of dogs over 10 years of age are diagnosed with cancer; 90 million pet dogs in the US) and high unmet need (Nu.Q Vet was the first non-invasive cancer screening test launched in the US).

Although early in its commercialization efforts, Nu.Q Vet could be a significant revenue contributor, contingent on appropriate market acceptance. A perceived lower sophistication to next-generation sequencing (NGS) tests can be a downside risk but is counterbalanced by the materially lower price (target price of $50 versus $1,000–1,500) and faster turnaround time (3–5 days vs 10–15 days), which should come down further following the launch of the Heska-partnered PoC (point of care) test in H123. The larger reference labs opportunity is covered with the recent distribution deal with IDEXX, providing VolitionRx access to over 50,000 veterinary practices globally, and materially expands the test's scope and potential.

In August 2022 we published a separate report on VolitionRx's NETosis business (Nu.Q NETs), which can be accessed here.

Pharma and biotech

17 January 2023

Price	**$2.4**
Market cap	**$138m**

Share price graph

Share details

Code	VNRX
Listing	NYSE
Shares in issue	57.5m
Gross cash (at end Q322)	$16.4m

Business description

VolitionRx is a clinical diagnostics company developing easy-to-use and cost-effective blood tests to diagnose a range of diseases in humans and animals including cancer and sepsis. Diagnostic Nu.Q® tests are based on the science of Nucleosomics™, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluids.

Bull

- The pet cancer screening and diagnostic market remains underserved with a clear unmet need.
- Relatively lower regulatory hurdles and cash reimbursement on veterinary side. This allows the company to monetize learnings/technology.
- Nu.Q Vet is the first non-invasive, blood-based screening test to be launched for canine cancers that is relatively more affordable.

Bear

- Competing with more sophisticated (lab-based and more expensive) diagnostic tests for the same market.
- Difficulty in gaining acceptance for Nu.Q Vet as a first-line screening test alongside regular wellness checks.
- Potential challenges in winning other partnering deals.

Analysts

Soo Romanoff +44 (0)20 3077 5700

Jyoti Prakash, CFA +44 (0)20 3077 5700

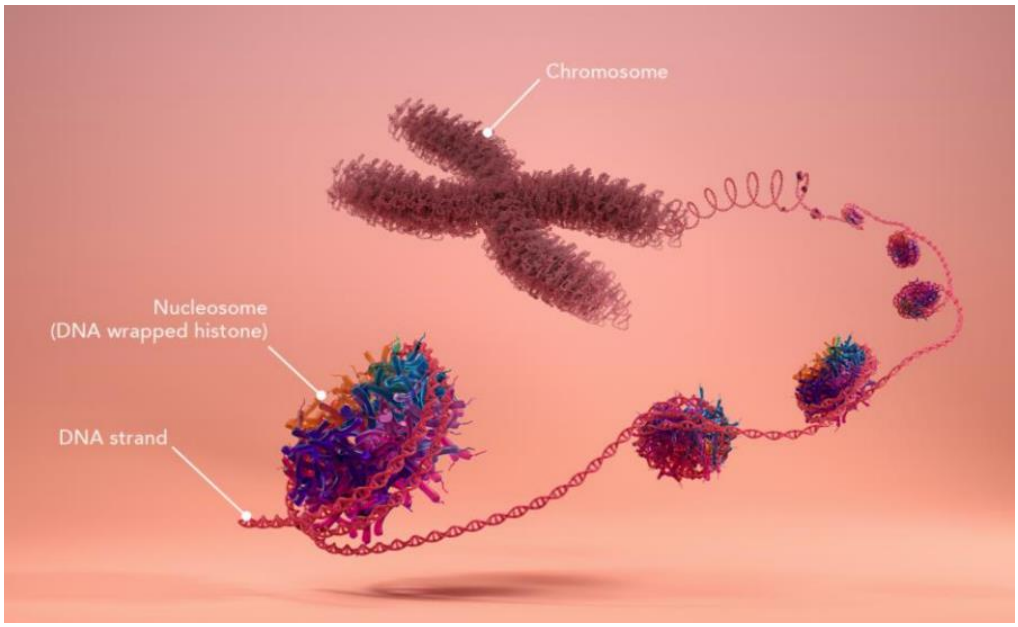
healthcare@edisongroup.com

Edison profile page

Nu.Q platform: Simpler way to detect complex diseases

VolitionRx's product pipeline is underpinned by its Nu.Q technology, which is centered on the quantification and detection of nucleosomes (which are essentially strands of DNA wrapped around proteins called histones), Exhibit 1. When a cell dies, DNA strings are broken up into individual nucleosomes, which are then released into the bloodstream. As cancer is generally characterized by high levels of cell death, nucleosome levels tend to rise in cancer patients. Circulating nucleosomes and nucleosome modifications are known cancer biomarkers but are typically not targeted by diagnostics tools. VolitionRx has developed ELISA-based assays to characterize and quantify nucleosome-based biomarkers in the hope of identifying signatures indicative of cancer(s). The platform is the first analytically validated, standardized clinical assay for the detection of nucleosomes in blood, which is a different approach to the traditional diagnostics and has broader applications across specialties. A key aspect of the platform is that it can detect nucleosome changes from very early-stage diseases, enabling timely detection and an earlier treatment start, potentially improving the disease prognosis. However, one limiting factor of nucleosomes is that they can also increase in situations unrelated to cancer, such as in the case of infectious diseases, requiring further validation through follow-up testing. VolitionRx is investigating the use of sequencing and mass spectrometry as a supplement to its test to derive deeper inferences from nucleosomes, such as cancer subtypes and specific mutations.

Exhibit 1: The structure of nucleosomes



Source: VolitionRx corporate presentation deck, May 2022

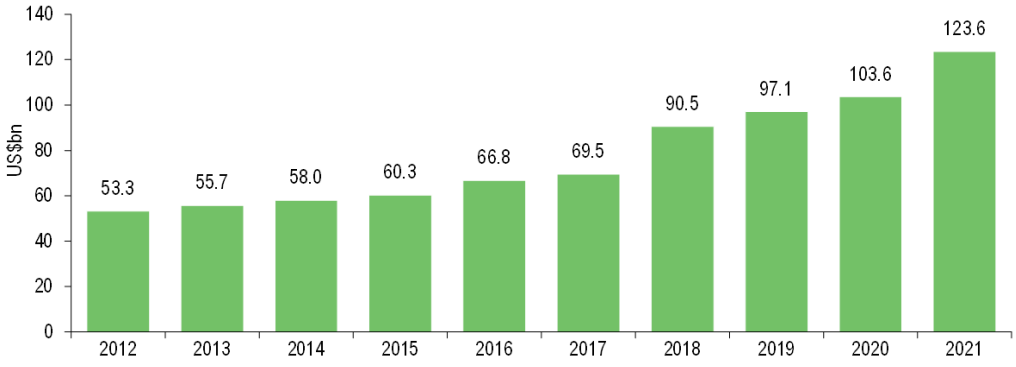
Veterinary healthcare diagnostics landscape underserved

Cancer remains a key disease burden and continues to be the subject of significant research and development. While the area of human diagnostics and screening programs has seen several advancements, animal diagnostics remains underserved, creating a sizeable market opportunity for novel devices and diagnostic screening tests. The rising rates of pet ownership, particularly in the wake of the COVID-19 pandemic (with pets providing companionship and reducing stress), has also translated to increased awareness and need for pet healthcare.

According to the American Pet Products Association, 70% of US households keep pets and the total pet industry spend stood at $123.6bn in 2021, a 19% jump on the previous year's figure of $103.6bn and a CAGR of 9.8% over 2012-21 (Exhibit 2). Veterinary surgical services make up the

bulk of the spend ($458/dog and $201/cat). According to Grand View Research, the global veterinary diagnostics market was valued at $6.63bn in 2021 and is expected to grow at a CAGR of 11.2% from 2022 to 2030. VolitionRx could target the mass markets from the perspective of both the reference lab and PoC as its partnerships allow the company to be provider need agnostic.

Exhibit 2: US annual pet care spend ($bn)



Source: APPA U.S. Pet Industry Expenditure Report

Highlighting the need for improved canine cancer screening

With 90 million dogs and approximately six million cancer diagnoses each year in the US, the pet dog market is very large and cancer diagnostics represent a high unmet need. The incidence of cancer in dogs is much higher than in humans (2.5 times, despite a materially lower population) and remains the largest cause of deaths in dogs over the age of two. The statistics are jarring: one-third of all dogs and 50% of dogs over the age of 10 will be diagnosed with cancer during their lifetime. Yet, options for canine cancer screening have underwhelmed in comparison to the well-entrenched, structured, and robust screening programs in human medicine. To date, there have been no reliable non-invasive tests to diagnose early-stage cancer in dogs, with most animals diagnosed with advanced disease. Moreover, available diagnostics include expensive imaging or invasive operations, which must be done under anesthesia, and limits the use of these options due to the high costs attached.

Real-world evidence shows that cancer is often treatable if caught early and periodic cancer screenings are the best way to detect, monitor and manage the disease burden. In humans, cancer screening programs such as mammograms, human papillomavirus tests and Pap tests for women, prostate specific antigen testing for men and colonoscopies have been proven to help detect cancers at earlier stages (and are covered by most insurance policies), when treatment is more effective, and a cure is more likely to be achieved. Just as in humans, the primary objective of canine cancer screening should be to detect cancer at an early stage to maximize treatment efficacy and achieve best possible clinical outcomes. Although further research is needed to ascertain if early cancer identification and treatment in canines can mirror the outcomes seen in human subjects, potential advantages of population-level screening programs are evident. Established veterinary organizations have voiced the importance of earlier diagnosis, with the American Animal Hospital Association stating that 'half of all canine cancers are treatable if caught early enough'.

A non-invasive cancer detection method requiring only routine blood collection may therefore encourage adoption and compliance of canine cancer screening tests. A relatively inexpensive and simple test that could easily be incorporated as part of annual veterinary checks, such as Nu.Q Vet, should therefore be able to fill this demand gap for early screening of dogs at high risk of cancer (ie those over the age of seven years, large breeds and purebreds).

The Nu.Q Vet opportunity

Nu.Q Vet is the veterinary application of VolitionRx's core Nu.Q platform and its first product to commence commercialization. The assay was developed in collaboration with Texas A&M University, one of the top veterinary schools in the US, in return for a 12.5% stake in VolitionRx's veterinary subsidiary (Volition Veterinary Diagnostics Development LLC). A pilot study in early 2018 concluded that the same assays used in humans can also be used to detect nucleosomes in samples from dogs diagnosed with cancer. In fact, it is believed that histones and nucleosomes are very similar across all mammalian species, including animals such as dogs and cats, and therefore the same test can be utilized in the veterinary space as well.

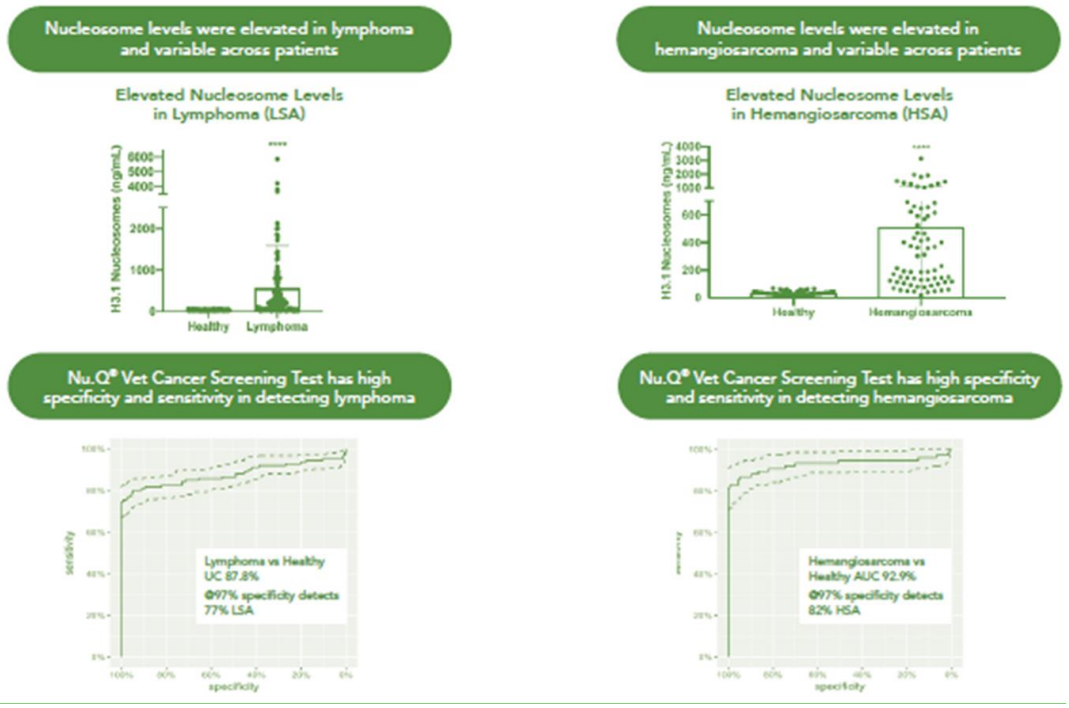
The Nu.Q Vet cancer screening test is currently available, on prescription, for cancer screening in dogs. It detects a range of cancers, most notably systemic cancer (76% detection) including lymphoma (77%), the leading canine cancer. The caveat here is that while results from the Nu.Q Vet test indicate the likelihood of cancer being present, it is not able to confirm the presence of cancer with certainty, or the type of cancer and its severity/stage. Results from the test need to be interpreted by a veterinarian in the context of each patient's medical history and clinical presentation. Moreover, a confirmatory cancer evaluation is required to establish a definitive diagnosis. The benefit of the test comes from ease of use, convenience, and affordability.

The test was launched in the US market in December 2020, making it the first ELISA cancer screening test available in veterinary medicine, and is currently available to veterinarians through the GI Lab at Texas A&M University across the US. The Nu.Q Vet test was also launched in Singapore in April 2022, where it is marked and sold by distribution partner SAGE Healthcare to centralized veterinary labs in the country. According to the latest available information, 2,000 units have been sold to date through Texas A&M in the US and are available to veterinarians at $68/test plus shipping. With increasing scale and volumes, the eventual target is to get the list price down to $50/test. Additionally, these tests do not require specialist equipment or labs, which is an advantage for vet practices.

Validated by encouraging clinical outcomes

Data from an initial study conducted by the Texas A&M University were published in two peer-reviewed journals at the BMC Veterinary Research in 2021 (lymphoma, hemangiosarcoma). The study enrolled 336 dogs (126 dog with lymphoma, 76 dogs with hemangiosarcoma and 134 healthy controls). The population was chosen to reflect a broad selection of breeds, weights and cancer stages. The objectives of the study were to quantify and better characterize nucleosomes in dogs with various stages of lymphoma and hemangiosarcoma using the Nu.Q Vet ELISA-based assay. The test results were encouraging and successfully concluded that nucleosomes levels are consistently elevated in both cancers (see Exhibit 3). At 97% specificity the Nu.Q Vet cancer screening test detected 82% of hemangiosarcoma cases and 77% lymphoma cases when compared to healthy controls.

Exhibit 3: Clinical study results



Source: VolitionRx company reports

The initial study was subsequently expanded to include dogs with a variety of other common cancers. In addition to the aforementioned cohort of 336, a further 326 dogs were evaluated with malignancies including osteosarcoma (n=49), soft tissue sarcoma (n=51), malignant melanoma (n=49), mast cell tumors (n=126) and histiocytic sarcoma (n=26). The dogs afflicted with cancer ranged in age from 1–19 years (median nine years) and weighed 5–74.5kg (median 30.9kg). The aim of the expanded study was to evaluate the sensitivity and specificity of circulating nucleosome concentrations in a number of cancers using the Nu.Q Vet screen, to build understanding of cancer types most associated with elevated nucleosome levels.

A total of 662 dogs (including 528 dogs with cancer and 134 healthy dogs) were included in the initial and expanded study and statistical analysis from 504 dogs with cancer was published in a BMC Veterinary Research paper in August 2022 (Exhibit 4). The study concluded that the Nu.Q Vet cancer test was able to detect 76% of systemic cancers – lymphoma (77%), hemangiosarcoma (82%) and histiocytic sarcoma (54%) – and was able to identify 50% of all cancers researched at 97% specificity.

Exhibit 4: Sensitivity/specificity of plasma nucleosomes in detecting canine cancers

Cancer Histology	Number of cases	Increased Nu.Q® level	Sensitivity	Specificity	AUC
All Cancers	504	251/504	49.8%	97%	68.74%
Lymphoma	126	97/126	76.98%	97%	87.83%
Hemanglosarcoma	77	63/77	81.82%	97%	91.74%
Histiocytic Sarcoma	26	14/26	53.85%	97%	83.01%
Hist Sarc—bone	5	1/5	20%	97%	81.04%
Hist Sarc Visceral	21	13/21	61.9%	97%	83.48%
Melanoma (all)	49	21/49	42.86%	97%	70.36%
Melanoma [22]	42	21/42	50%	97%	75.05%
Melanoma (cutaneous)	7	0/7	0%	97%	42.22%
Mast Cell Tumor	126	24/126	19.05%	97%	43.68%
Grade 1 MCT	9	3/9	33.33%	97%	44.1%
Grade 2 MCT	87	10/87	11.49%	97%	11.49%
Grade 3 MCT	26	9/26	34.62%	97%	60.7%
Osteosarcoma	49	17/49	34.69%	97%	60.17%
Soft tissue sarcoma	51	15/51	29.41%	97%	48.19%

Source: VolitionRx company reports

Optimized through effective partnering

The end-user market for Nu.Q Vet encompasses veterinary practices, clinics and animal hospitals. It is estimated that there are 28,000–32,000 veterinary practices operating in the US. While still fairly fragmented, the industry has seen an increasing trend towards consolidation, with 20% of the clinics owned by corporates or private equity. The largest corporate player in the space is Mars Petcare, which owns a network of over 2,000 clinics following acquisitions of large veterinary chains such as VCA, Banfield and BluePearl. In 2017, VCA, North America's largest provider of veterinary services (c 800 clinics), was acquired by Mars for $9.1bn.

When it comes to diagnostic testing, the protocol is fairly standard. There are two ways veterinarians can provide these services: PoC testing (which requires the diagnostic equipment and assays to be installed in-house) or reference labs (where the sample is collected at the clinic but then shipped out to centralized labs for analysis). While routine testing (such as basic blood tests) can be performed in-house, more complicated samples (such as tissue biopsies) are typically sent out to the reference labs for testing. The benefit of PoC testing is the quick turnaround time (a few minutes or hours versus multiple days taken by reference labs); this is offset by upfront capex and/or minimum purchase order volumes requirements as well as the perceived lower accuracy of these tests. Unlike the veterinary clinic market, the diagnostics space in the US is highly consolidated and dominated by a few large players (see Exhibit 5).

Exhibit 5: The veterinary diagnostics market in the US

Reference laboratories		PoC	
Company	**Market share**	**Company**	**Market share**
IDEXX Laboratories	~45% (c 50 labs)	IDEXX Laboratories	~65%
Mars Petcare, Antech	~45% (c 60–65 labs)	Zoetis, Abaxis	~25%
Zoetis	~2–5% (c 15 labs)	Heska	~12–15%

Source: Company documents, Edison Investment Research estimates

The trend towards downstream consolidation has been felt more acutely in the veterinary diagnostics space, as evidenced by the recent spate of big mergers and acquisitions in the industry. Exhibit 6 presents a few selected deals in the past few years.

Exhibit 6: Recent major deals in the veterinary diagnostics space

Date	Acquiror	Target	Deal value	Notes
April 2020	Heska	Scil Animal Care	$110m	Scil was a leading European provider of veterinary PoC laboratory and imaging diagnostics, with headquarters in Germany and operations in France, Italy, Spain and Canada. Following the acquisition, Heska expands reach to 25 countries with strong market shares – US (12.5%), Canada (13%), Germany (40%), Spain (40%), France (30%), and Italy (19%)
November 2019	Zoetis	ZNLabs	N/A	ZNLabs was a full-service veterinary clinical reference laboratory company with a network of seven reference labs across the US
July 2018	Zoetis	Abaxis	$2bn	Abaxis was a developer, manufacturer and marketer of diagnostic instruments for veterinary PoC services. The acquisition marked Zoetis' foray into the veterinary diagnostics space

Source: Various company documents; Edison Investment Research

The veterinary labs are highly incentivized by these diagnostic players to sign long-term contracts (through rebates and discounts, among other things) and relationships therefore tend to be highly sticky. The overarching takeaway is that for any new diagnostic test seeking to make inroads in veterinary clinics, the most efficient way would be to secure partnership or licensing deals with one or more of the top diagnostic players.

With this understanding, VolitionRx has been seeking to expand market coverage by securing partnership and licensing agreements with larger diagnostics players in the veterinary space. In March 2022, VolitionRx signed a $28m exclusive global licensing and supply agreement with leading US veterinary diagnostic company Heska Corporation (HSKA) to sell its Nu.Q Vet cancer screening test for companion animals at PoC. The deal includes a number of milestone payments (including a $10m upfront payment received in Q122) in addition to an ongoing revenue stream for the supply of kits and key components. As part of the deal, Heska also holds non-exclusive rights to sell the test kit through its network of central reference laboratories. The PoC variation of the current ELISA-based test is under development and the company expects to launch by the first half of 2023. It will be operated on Heska's proprietary Element i+ bioanalyzer device, which is a cartridge-based benchtop device that can be installed and used in veterinarian clinics and hospitals. The Element i+ bioanalyzer was developed by Heska in collaboration with diagnostic-testing company LightDeck Diagnostics (MBio Diagnostics) under an exclusive partnership agreement signed in 2018. As part of the agreement, the companies have been collaborating on developing next-generation, rapid, low-cost, PoC diagnostics for companion animals. In September 2022, Heska announced the acquisition of LightDeck for $38.7m (the deal was completed on 3 January 2023). We expect the acquisition to allow Heska to generate manufacturing efficiencies allowing for improved cost savings, manufacturing scale-up (including the Element i+ bioanalyzer) and accelerated test menu expansion, including VolitionRx's Nu.Q Vet cancer screening test.

In October 2022, VolitionRx signed a supply and distribution agreement with IDEXX, a global leader in veterinary diagnostics with over 80 reference labs (including c 50 in the US) servicing 50,000 veterinary practices in over 175 countries. The deal is a 10-year non-exclusive licensing agreement to commercialize the Nu.Q Vet cancer test for canine cancer screening and monitoring in IDEXX's reference labs. We see this deal as a key milestone for the company, given that IDEXX holds upwards of 45% market shares in the US reference labs market (with a number of veterinary practices contractually bound to use its services). Together with Heska's PoC offering, this should allow VolitionRx to target the marketplace in its entirety and help optimize the potential of its Nu.Q Vet screening test. We also note that because the deal with IDEXX is not exclusive, it allows for VolitionRx to pursue similar arrangements with other larger reference lab groups, such as Antech, expanding the potential market opportunity.

Differentiated positioning versus competition

While cancer diagnostics for humans has seen continued innovation, the veterinary equivalent has notably lagged until recently. As per our understanding, since 2019 there have been four new

canine cancer diagnostic tools launched in the US, of which only Nu.Q Vet is based on the ELISA platform, with all other tests employing next-generation sequencing (NGS) (Exhibit 7).

Exhibit 7: Canine cancer diagnostic competitive landscape (US)

	VolitionRx	PetDx	One Health	TGen-Vidium Health
Product	Nu.Q Vet	OncoK9	FidoCure	SearchLight DNA
Description	Blood-based detection of cancer using propriety nucleosomes platform	Liquid biopsy test utilizing next-generation sequencing	Next-generation DNA sequencing to identifying genetic mutations that cause cancer in dogs	Genomic test to identify any of the nearly 120 known cancer-associated genetic mutations in dogs.
Launch	December 2020	June 2021	April 2019	September 2020
Early cancer screening	Yes	Yes	No	No
Tissue sample/blood volume	Blood plasma (1–2ml)	Blood serum (14–17ml)	Tissue sample	Fine-needle aspirates (FNA), formalin-fixed, paraffin-embedded (FFPE) tissue, or fresh frozen tumor samples
Technology	ELISA	Next-generation sequencing	Next-generation sequencing	Next-generation sequencing
Turnaround time	3-5 days (potential to go down to a few minutes in the PoC setting)	9–15 days	14–21 days	9–12 days
Price/test	$50–122	$400–1,000	$1,500+	$1,000
Partnerships	Heska, IDEXX, Texas A&M GI Lab.	IDEXX, Antech	IDEXX	Antech
Reimbursed	No	No	Yes	Yes

Source: Company reports, Edison Investment Research

Of the four newly launched tests, two (FidoCure and SearchLight DNA) are invasive tissue biopsy-based tests likely to be used in more advanced cancer cases and therefore we do not see these as being directly comparable to the front-line positioning of Nu.Q Vet, which is a simple blood test. We expect the biggest head-to-head competition to come from PetDx's OncoK9 liquid biopsy test, which, although not fully comparable, is similar to Nu.Q Vet in that it is also positioned as an early screening test to detect cancer signals. Both tests are currently not designed to identify cancer types, unlike FidoCure and SearchLight DNA.

One key limiting factor of the Nu.Q Vet test is, being a single-biomarker test based on the older-generation ELISA technology, in its current form it can detect only hematological cancers such as lymphoma and hemangiosarcoma, whereas OncoK9 can detect and identify over 30 canine cancers with a 98.5% specificity. However, we see the Nu.Q Vet test as having several clear advantages over the competition. First, Nu.Q Vet's lower price point (target of $50/test vs $400–1,000 per test for OncoK9) and rapid turnaround (3–5 days versus 9–15 days) should position the company to better serve as an early diagnostic tool as part of the annual companion animal's wellness check. Second, we see the foreseeable launch of a PoC version as a key differentiator and key to unlocking value for Nu.Q Vet, allowing it broader coverage of the market, both in terms of being a diagnostic test as well as a subsequent monitoring tool. Partner Heska plans to price the PoC version even more competitively (sub-$50/test) and this, alongside ease of use (vet's office versus remote reference labs), a materially lower turnaround time for results (a few minutes versus a few days) and a much smaller sample size requirement (a few drops of blood versus 14–17ml in the case of OncoK9), should accord Nu.Q Vet key competitive advantages over peers, in our opinion. Further out, foray into the monitoring space (which would require more frequent testing and therefore will come with higher volume sales) as well as testing for other companion animals (such as cats) should be the key value enhancers over competitors.

The wellness check market in the US is relatively mature and, according to the American Veterinary Medical Association, 78.8% of surveyed dog owners bring their dog in for a wellness check at least

once a year. Given that wellness panels are generally not reimbursed in the US, we expect the lower price tag for Nu.Q Vet to act as a lever to receiving the go-ahead from pet owners. We expect the Heska-partnered PoC test, once launched, to be the key focus area for VolitionRx and where the company has potential to develop its niche. However, given that PoC tests are generally associated with relatively lower comparative accuracy than the lab counterparts, the company would have to ensure that its PoC test maintains similar specificity to its reference lab optimized counterpart on the market.

Market acceptance could translate to a sizable potential

A routine wellness check for pet dogs can cost anywhere between $50 and $250 per annual visit, with some of the common tests falling in the range of $25–100 (such as blood tests: $90–110, fecal examinations: $25–45, and vaccine boosters: $18–25). Testing of geriatric dogs (over seven years of age) is usually more comprehensive, requiring an additional spend of $85–100. In this context, we believe that Nu.Q Vet, with a target price tag of $50/test, is well-positioned to gain acceptance from both veterinarians and pet owners as a wellness screen, especially for geriatric dogs. However, given that the test is currently at the very early stages of commercial rollout, the scale and scope of success will be contingent on effective outreach efforts, including creating awareness and educating relevant stakeholders. In this regard, we expect leveraging of partnerships and collaborations with larger diagnostics players to play a key role in mapping the market for Nu.Q Vet, as discussed earlier in this note.

If successful, given the market scope, even a small percentage of the canine cancer screening pie should add up to sizeable revenue potential. Cancer is the number one cause of death in adult dogs and reports suggest that c 50% of all dogs in the US are over seven years of age (the primary target market for Nu.Q Vet), which translates to around 45 million dogs (over seven years of age) undergoing annual wellness checks. Assuming a conservative 10% penetration rate, this would translate to ~4–4.5m Nu.Q Vet cancer tests per year in the US alone. Our understanding is that VolitionRx aims to generate a 20–25% margin on the Nu.Q Vet sales (which translates to $10–12.5/test) under the licensing agreements. Assuming an average $10/test, it could translate to revenues of $40–45m per year, a figure that is realistically achievable, in our opinion. Moreover, being a low capex/opex business (no need for specialized equipment or labs and direct sales/marketing efforts), we expect much of the benefits to flow down to the bottom line, making for an attractive investment proposition.

VolitionRx's longer-term plans include launching the PoC canine test, expanding the utility of the PoC test into monitoring (for which the application is expected in 2023; this should translate into significantly larger volumes, given the requirement for administering the test on a periodic basis), launching a cancer screening and monitoring test for cats (testing initiated) and other pet species, and possibly expanding the test for the diagnosis of sepsis in companion animals using the company's Nu.Q NET technology (discussed in detail in a separate note). Each of these holds potential to materially expand the market opportunity for VolitionRx.

Summary

In this note we have discussed VolitionRx's veterinary business, in particular its Nu.Q Vet cancer screening test, the company's first commercialized product, and the near-term monetization opportunity. Given the large market size, unmet demand and ease-of-use benefits, we see the building blocks for strong growth potential, contingent on effective execution of the market outreach strategy and commercialization plans. The next six to 12 months will be crucial as the company aims to ink new partnerships, establish its supply and distribution agreement with IDEXX and launch its PoC product, which we expect will be the key differentiating factor from competing products on the market. In the longer term, continued enhancements of the products (such as

expanding the range of cancers detected and improving specificity) would be the required drivers for consistent growth.

In August 2022 we published a review of VolitionRx's human assay (diagnostics) business potential in high-risk infectious diseases (such as COVID-19) and sepsis in a separate report, which can be accessed here.

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia