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Viveve Medical (VIVE-NASDAQ)

VIVE: Compelling SUI Feasibility Study 6-Month Data. SUI LIBERATE RCTs On-Deck

We use a 10-year DCF model to value VIVE. We have revenue growing from $15.3M in 2016 to $44M in 2020 and to approximately $100M in 2026. Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. Based on our DCF model, VIVE is valued at approximately $7.75/share.

Current Price (06/28/18)	$2.50
Valuation	**$7.75**

OUTLOOK

Last week Viveve announced what we would characterize as potentially compelling 6-month data from its ongoing SUI 12-month feasibility study. As a refresher, this is the second formal pilot/feasibility study assessing the Viveve System in the treatment of mild-to-moderate SUI.

While, given this was a small single-arm study with data only through 6 months, we can not draw concrete conclusions in terms of efficacy . But, as management noted on the call, combined with positive data of the prior n=10 pilot study, results to-date certainly appear to support the hypothesis that the Viveve system may have real clinical utility in improving SUI symptoms. Given that, from a regulatory standpoint, efficacy through 12 months is what important - we should know a lot more in terms of the potential utility of the Viveve system in SUI when 12-month results of this study are available.

In the meantime, VIVE anticipates making their IDE filing for LIBERATE U.S. in the very near-term - mentioning on the call that they expect to file by the end of June or early July. They also hope to have approval from Health Canada around the same time to begin the LIBERATE international study. At that time we should know the complete trial designs - including all endpoints.

SUMMARY DATA

52-Week High	**$7.73**
52-Week Low	**$1.60**
One-Year Return (%)	**-62.15**
Beta	**-0.47**
Average Daily Volume (sh)	**589,603**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$78**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**67**
Insider Ownership (%)	**35**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**115.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**
	High,

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	3041 A	3073 A	4070 A	5101 A	15288 A
2018	3699 A	4799 E	5484 E	7235 E	21217 E
2019					34910 E
2020					43478 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.57 A	-$0.54 A	-$0.50 A	-$0.53 A	-$2.12 A
2018	-$0.49 A	-$0.38 E	-$0.38 E	-$0.37 E	-$1.61 E
2019					-$1.18 E
2020					-$0.98 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Compelling SUI Feasibility Study 6-Month Data: *Meaningful Improvement On All Endpoints, Will Support IDE Filings…*

Last week Viveve announced what we would characterize as potentially compelling 6-month data from its ongoing SUI 12-month feasibility study. As a refresher, this is the second formal pilot/feasibility study assessing the Viveve System in the treatment of mild-to-moderate SUI (see below for refresher on the first). Listed under clinicaltrials.org Identifier: NCT03066180 (http://bit.ly/2k3OX9p), the single-arm, 36-subject study is being conducted at Dr. Bruce Allan's Allan Centre (Dr. Allan was also the principal investigator for the VIVEVE I vaginal laxity/sexual function study) in Calgary, Canada. Protocol allowed for one (just following baseline) or two (6 – 12 weeks later) Viveve treatments.

While only a single-arm feasibility study, it was clearly designed to be consistent with FDA's recommendations for SUI-device pivotal studies (FDA's guidance (http://bit.ly/2Iy2orT) for *Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence).* This includes the inclusion and exclusion criteria as well as the choice of primary and secondary endpoints. Relative to SUI severity, inclusion criteria included diagnosis of mild-to-moderate SUI as determined by one-hour pad weight test (using International Continence Society definitions; mild = 1-10g, moderate = 11-50g, severe = > 50g).

Primary endpoint is reduction in 1-hour pad weight versus baseline. Secondary measures are the 7-day bladder voiding diary and composite scores from three quality-of-life oriented questionnaires; UDI-6 (Urogenital Distress Inventory-Short Form), IIQ-7 (Incontinence Impact Questionnaire) and ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form).

Results: *83% Response Rate on Primary Endpoint, 73% Average Reduction of Urine Leakage…*

Of the 36 enrolled participants, 28 completed full follow-up (i.e. were assessed on all endpoints) through 6 months and one completed full follow-up except for the 7-day voiding diary through 6 months. Management mentioned on the call that while the two-treatment protocol was used with a few women, that there was not an obvious difference in efficacy as compared to a single treatment (a single treatment will be employed in upcoming studies). Results, which are also in the table below (from VIVE's press release), were;

- **1-hour pad weight test:** the 1-hour pad weight test is also expected to serve as the primary endpoint in the two anticipated upcoming SUI LIBERATE studies. As measured by the 1-hour pad weight test (i.e. primary endpoint), average aggregate urine leakage decreased by 73% from baseline (6.2g vs 1.7g) and 83% (24 of 29) of women experienced improvement. For reference (and discussed in more detail below), FDA recommends (for the design of pivotal SUI studies) defining 'clinically meaningful improvement' as a reduction in urine leakage of 50% or more. Additionally (as it relates to the primary endpoint), 66% (19 of 29) of women met the clinically meaningful definition of 'dryness' - which is defined as urine leakage of one gram or less.

- **7-day voiding diary**: the 7-day voiding diary, along with the 1-hour pad weight test, are two measures that FDA recommends using as primary endpoints for pivotal SUI device studies. Based on the 7-day voiding diary, VIVE's feasibility study showed that, through 6 months (n=28), average aggregate incontinence episodes decreased by 50% from baseline (2.0 vs 1.0) and 79% (22 of 28) of women experienced an improvement in incontinence episodes. For reference, FDA recommends defining 'clinically meaningful improvement' for the 7-day voiding diary as greater than 50% reduction in incontinence episodes compared to baseline. While VIVE did not report on 'dryness' as measured by the 7-day voiding diary (defined in our endpoints discussion below), that may be included in the 12-month data (which, potentially could be available late this year or early 2019).

- **QoL questionnaires**: VIVE reported that, through 6 months, 'clinically meaningful' improvement was achieved on the composite scores of the three QoL questionnaires. Additionally, 69%, 83% and 86% of women reported improvement based on the IIQ-7, UDI-6 and ICIQ-UI-SF questionnaires. We discuss QoL measures for SUI device studies in more detail below.

SUI Feasibility 6-month Results

	1-HOUR PAD WEIGHT	DAILY INCONTINENCE EPISODE FREQUENCY	UDI-6	IIQ-7	ICIQ-UI-SF
BASELINE SCORES (N=29)	6.2 g	2.0 (N=28)	44	36	10.9
SCORES AT 6 MONTHS (N=29)	1.7 g	1.0 (N=28)	21	18	6.8
% REDUCTION FROM BASELINE AT 6 MONTHS (N=29)	72.6%	50.0% (N=28)	53.6%	49.2%	38.0%
RESPONDER RATE AT 6 MONTHS (IMPROVEMENT FROM BASELINE) (N=29)	82.8%	78.6% (N=28)	82.8%	69.0%	86.2%

SOURCE: Viveve Medical June 18, 2018 press release

- **Safety**: as has largely been the case with Viveve treatment of vaginal laxity, there were no device-related adverse events through 6 months in this SUI feasibility study.

While, given this was a small single-arm study with data only through 6 months, we can not draw concrete conclusions in terms of efficacy . But, as management noted on the call, combined with positive data of the prior n=10 pilot study (see below), results to-date certainly appear to support the hypothesis that the Viveve system may have real clinical utility in improving SUI symptoms. Given that from a regulatory standpoint, efficacy through 12 months is what is important - we should know a lot more in terms of the potential utility of the Viveve system in SUI when 12-month results of this study are available.

LIBERATE Studies:
In the meantime, VIVE anticipates making their IDE filing for LIBERATE U.S. in the very near-term - mentioning on the call that they expect to file by the end of June or early July. They also hope to have approval from Health Canada around the same time to begin the LIBERATE international study. At that time we should know the complete trial designs - including all endpoints. See our Appendix for refresher on both studies.

Relative to FDA's guidance on SUI endpoints…

- Primary endpoints: FDA recommends that a urinary incontinence device pivotal trial use one or both of the following measures as primary endpoints: urine leakage as assessed by pad weight test and/or reduction in the number of incontinence episodes per day. If only of the two is used as the primary endpoint, FDA further recommends using the other as a secondary endpoint
  - pad weight test: with the 1-hour pad weight test (which can also be performed over a 24-hour period), the subject wears a pre-weighed pad, drinks a specified amount of liquid and then performs certain activities (such as walking, climbing stairs, coughing etc). After one-hour, the pad is again weighed to determine the amount of urinary leakage. Relative to the what is considered clinically meaningful (with the objective on dryness) with the one-hour pad weight test, FDA recommends defining 'dryness' as an increase in pad weight of less than 1 gram and defining 'improvement' as a 50% or more decrease in weight from baseline
- Reduction in incontinence episodes: FDA recommends using a standardized voiding diary to document fluid intake and the number of incontinence episodes over seven consecutive days. The average number of incontinence episodes per day is then compared to baseline to determine effectiveness. With the 7-day voiding diary, FDA recommends using 'zero incontinence episodes per day' as the clinically meaningful definition of 'dryness' and 'greater than 50% reduction' (from baseline) as clinically meaningful improvement
- Secondary endpoints: FDA's general guidance relative to stress urinary incontinence clinical trials is to choose secondary endpoints which will provide additional evidence of the efficacy and safety of the device as well as to support performance and labeling. Among the possible secondary endpoints, FDA recommends considering measures related to quality of life (via questionnaires), sexual function, leak point pressure, bladder voiding and patient satisfaction. Specifically as it relates to;

- QoL: FDA's guidance notes that since UI "is strongly associated with impairment of quality of life," that they recommend using validated QoL measures (as secondary endpoints) such as the Incontinence Quality of Life (I-QOL) questionnaire (as an example of one of many QoL measures that could be employed) and pre-specify the minimum delta that represents a meaningful improvement in QoL. FDA's guidance further recommends that choice of QoL measures should consider the specific populations and settings where they were developed and validated. FDA references The 3rd International Consultation on Incontinence as a source for choosing appropriate QoL measures, which includes the three QoL measures used in VIVE's feasibility study (UDI-6, IIQ-7 and ICIQ-UI-SF). While we may have more discussion on the topic after we know specifics of design of the two LIBERATE studies, we think the most important take-away at this point is that the three QoL measures used in this ongoing feasibility study are definitely validated clinical endpoints
- Sexual function: based on close proximity to genitalia, FDA recommends consideration of a sexual function related measure (such as a validated sexual function questionnaire)
- Patient satisfaction: incorporate a validated patient satisfaction questionnaire which asks the participant to rate the improvement (as compared to baseline) on several topics related to how SUI effects their lives and livelihoods

SUI Market

According to the National Women's Health Resource Center[1] (NWHRC), SUI is estimated to effect 30% of all adult women in the U.S. (i.e. ~31M Americans) and of those with SUI, 53% have "slight" incontinence while 17% have severe incontinence. SUI can be a significant hindrance to quality of life. The NWHRC reports that while 75% of women with the condition find it "bothersome" (or worse) and 60% make lifestyle changes as a result of it, as many as 50% to 75% of sufferers do not seek treatment (mostly as a result of embarrassment). SUI is more common among women that have had vaginal deliveries. We will expand on our discussion of the mild-to-moderate SUI market in future updates - hopefully corresponding to additional positive data from this ongoing 12-month feasibility study as well as the anticipated LIBERATE studies.

Valuation

Our Financial Model Assumptions…

So while certain differences in Thermage's product, target market, competitive landscape and early distribution capabilities may not provide a specific template for what to expect with the roll-out of the Viveve System, we think it is a useful gauge, at least in terms of illustrating the potential demand for the technology (which is essentially the same), pricing and utilization in the respective end-user markets.

In 2016 VIVE averaged a console unit placement rate of approximately 15 per month and utilization (based on number of treatment tips sold per console) averaged 1.6 tips per console per month. Utilization has substantially increased, however, and averaged 2.7 tips per console per month during 2017. We think revenue accelerates further on the backs of several catalysts including;

- U.S. sales: sales force tripled in size (including associates, practice development and regional mgrs.) since early 2017 and expected to expand again before end of 2018. Recent addition of practice development managers should help drive further growth in utilization
- Clinical Data / Regulatory: VIVEVE I data: showing statistically significant efficacy of Viveve treatment on sexual function and vaginal laxity. Data was published in the February 2017 issue of the Journal of Sexual Medicine and appears to have catalyzed adoption and utilization. IDE approval and start of VIVEVE II are major milestones and could further promote awareness and adoption. Initial SUI pilot study benefitted uptake – recently reported 6-month data from 2nd pilot/feasibility study could further stoke demand for SUI and spark additional adoption. Registrations studies, if successful, would likely further drive demand.

[1] National Women's Health Resource Center. Prevalence and Treatment Patterns of Pelvic Health Disorders Among U.S. Women. The Lewin Group. June 2007

- Recent key OUS launches: S. Korea, Taiwan, Mexico and Brazil all hold out-sized growth prospects, in our opinion, and almost certainly remain largely untapped. With regulatory clearance in 64 countries and others that could come online soon, the geographic footprint continues to rapidly grow.

With 16 capital reps as of YE2017, 24 today (and incremental adds later in 2018) and expected productivity gains as newer reps gain footing, we model 43 U.S. placements in Q2 and growing to 73 in Q4. We have OUS placements tracking at about 30% of the total. We model 300 total console sales in 2018 (vs 227 in 2017), including 210 in the U.S. (vs 160) – this implies slow but consistent productivity gains – which could prove conservative. We estimate consumable sales average ~2.9 per installed console per month in the remaining three quarters of 2018.

We think that if all goes well, in 2019 the U.S. label could possibly be expanded to a more substantive 'treatment of vaginal tissue to improve sexual function' indication. Coupled with a greater marketing push, expanded OUS distribution and additional clinical data to support sales, we think it is reasonable that Viveve could increase our estimated near-term unit placement rate. An SUI indication could also drive demand and potentially significantly expand the overall size of the targeted markets.

As it is now, we assume a ~18 - 20 average per month console unit placement rate from 2019 to 2024. This results in a total installed base of more than 2,500 units after ten years on the market, which compares to ~9,300 units with Thermage's products over roughly the same period of time. Again we account for the much more moderate roll-out with the Viveve System and much smaller market as compared to Thermage. We also think that a reasonable case would be made that our forecasted unit placement rate is conservative, particularly given that competition in Thermage's target market is much more intense and widespread than that of Viveve's.

We model utilization to improve with greater awareness of the benefits of non-invasive improvement in sexual function and vaginal tightening and, potentially with a generation of women that may feel less embarrassed about broaching the subject of vaginal laxity with their physician. Our modeled utilization improves from ~1.6x per month (average in 2016) to approximately 5x per month at year 2025.

DCF Values VIVE at $7.75/share

We use a 10-year DCF model to value VIVE. Using the inputs discussed above, we have revenue growing from $15.3M in 2016 to $43.5M in 2020 and to approximately $100M in 2026 (for reference, Thermage's sales were $50M+ at second year after ThermaCool launch). OpEx has trended higher than we had expected – which has prompted upward adjustments to our estimate operating expenses.

Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. While our out-year revenue has tweaked up, near-term revenue downward revisions and across-the-model OpEx adjustments offset the benefit. Based on our DCF model, VIVE is valued at approximately $7.75/share (revised down from $8/share). Our outlook and financial estimates are subject to change based on progress with expansion of distribution, results of clinical trial data and regulatory approvals, among other events. In addition, we have yet to include assumed market expansion related to any non-sexual function/vaginal laxity indications. As such, outsized adoption and utilization for indications such as SUI (or potentially others) could result in upside to our estimates, which should be assumed to be constantly under review and subject to updating.

FINANCIAL MODEL

Viveve Medical, Inc

	2016 A	2017 A	Q1A	Q2E	Q3E	Q4E	2018	2019	2020
Total Revenues	$7,141.0	$15,288.0	$3,699.0	$4,799.2	$5,484.4	$7,234.6	$21,217.3	$34,909.7	$43,477.5
YOY Growth	393.5%	114.1%	21.6%	56.0%	34.8%	41.8%	38.8%	64.5%	24.5%
Cost of Goods Sold	$4,612.0	$7,844.0	$2,352.0	$2,676.8	$2,790.9	$3,563.8	$11,383.5	$15,836.2	$17,737.1
Gross Income	$2,529.0	$7,444.0	$1,347.0	$2,122.4	$2,693.5	$3,670.8	$9,833.8	$19,073.5	$25,740.4
Gross Margin	35.4%	48.7%	36.4%	44.2%	49.1%	50.7%	46.3%	54.6%	59.2%
SG&A	$12,868.0	$28,831.0	$8,931.0	$9,176.1	$9,460.7	$9,998.3	$37,566.0	$45,766.6	$49,825.2
% SG&A	180.2%	188.6%	241.4%	191.2%	172.5%	138.2%	177.1%	131.1%	114.6%
R&D	$8,365.0	$12,343.0	$3,756.0	$3,671.4	$3,921.4	$4,268.4	$15,617.2	$11,415.5	$9,652.0
% R&D	117.1%	80.7%	101.5%	76.5%	71.5%	59.0%	73.6%	32.7%	22.2%
Operating Income	($18,704.0)	($33,730.0)	($11,340.0)	($10,725.0)	($10,688.5)	($10,595.9)	($43,349.4)	($38,108.6)	($33,736.8)
Operating Margin	-261.9%	-220.6%	-306.6%	-223.5%	-194.9%	-146.5%	-204.3%	-109.2%	-77.6%
Total Other Income (Expense)	($1,407.0)	($3,229.0)	($1,080.0)	($1,118.2)	($1,132.8)	($1,147.5)	($4,478.5)	($4,368.8)	($4,531.8)
Pre-Tax Income	($20,111.0)	($36,959.0)	($12,420.0)	($11,843.2)	($11,821.3)	($11,743.4)	($47,827.9)	($42,477.4)	($38,268.6)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-
Gain/(Loss) from Minority Interest	0.0	0.0	(249.0)	0.0	0.0	0.0	(249.0)	0.0	0.0
Net Income (continuing ops)	($20,111.0)	($36,959.0)	($12,669.0)	($11,843.2)	($11,821.3)	($11,743.4)	($48,076.9)	($42,477.4)	($38,268.6)
YOY Growth	61.8%	83.8%	117.7%	-41.1%	76.6%	12.6%	30.1%	-11.6%	-9.9%
Net Margin	-281.6%	-241.8%	-342.5%	-246.8%	-215.5%	-162.3%	-226.6%	-121.7%	-88.0%
EPS (continuing ops)	($2.18)	($2.12)	($0.49)	($0.38)	($0.38)	($0.37)	($1.61)	($1.18)	($0.98)
YOY Growth	-12.2%	-3.1%	-10.3%	-82.6%	-34.2%	-30.4%	-24.1%	-26.5%	-16.8%
Diluted Shares O/S	9,215	17,470	25,847	31,250	31,320	31,370	29,947	36,000	39,000

Brian Marckx, CFA

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APPENDIX

SUI REFRESHER

SUI Pilot Study
N=10, single-arm. Conducted in Calgary, Alberta by Dr. Bruce Allan (Dr. Allan was also one of the principal investigators of the VIVEVE I study). Safety and clinical measures were reported at months 4, 6, 9 and 12 months post-treatment. Press release mentions the study used a "proprietary treatment protocol" (specifics were not disclosed). Clinical measures included composite scores of the ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form) and UDI-6 (Urogenital Distress Inventory-Short Form) outcome questionnaires. Both questionnaires are industry-accepted as measures of urinary incontinence-related quality of life and symptom distress[2].

While VIVE provided only limited details, they did note (see slide from presentation, below) that at 12 months (9 patients were evaluable), 89% - 100% of patients were "responders" and mean improvement was 40% - 51% at 12 months based on the ICIQ-UI-SF and UDI-6 measures, respectively. Additional details, such as response and mean improvement at the earlier timepoints was not disclosed. It is also unclear whether other efficacy measures were included as part of the study. In terms of safety, the PR notes that no device-related safety issues were reported in any of the patients.

N=10 SUI Pilot Study Results at 12 Months

	UDI-6 (n=9)	ICIQ-UI (n=9)
Baseline Score	1567	9.4
12 Mos	767	5.7
% Reduction from Baseline	51%	40%
Responder Rate	100%	89%

SOURCE: Viveve Medical

Relative to the results of the study, Dr. Allan said, "In the pilot study, we found that SUI symptoms were significantly improved, providing strong support for the planned clinical registration studies and the potential to represent a major advance in the non-invasive treatment of SUI".

Pivotal Registration Trials Planned, To Kick-Off Following Go-Ahead From Regulators
VIVE hopes to go to conduct pivotal registration trials in both the U.S. and Canada – success of which would be used to support FDA and Health Canada filings seeking an indication for the temporary improvement of mild-to-moderate SUI symptoms. The Canadian study is also expected to accompany a CE Mark application (for European markets).

Design of the U.S. and Canadian studies are similar, although not identical. Importantly, both are multi-site RCTs. Both also use change from baseline in the one-hour pad weight test as the primary endpoint. With the pad weight test, the subject wears a pre-weighed pad, drinks a specified amount of liquid and then performs certain activities (such as walking, climbing stairs, coughing etc). After one-hour, the pad is again weighed to determine the amount of urinary leakage.

An Investigational Trial Application (ITA, analogous to IDE in U.S.) was submitted to Health Canada – VIVE noted on the 6-month SUI feasibility read-out call in June that they expect to hear back from HC in late June/early July, which is also when they hope to make their IDE filing. The 6-month feasibility study data will be used to support the IDE for approval to commence the U.S. Liberate study.

[2] Uebersax JS. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. Neurourol Urodyn. 1995;14(2):131-9.

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The U.S. and Canadian studies are expected to enroll 200 and 100 patients across 25 and 10 sites, respectively (~10 patients/site). Given the already sizeable installed base, we would expect enrollment may be accomplished fairly swiftly, assuming both the U.S. and Canadian studies can utilize certain of the current Viveve System practitioners' locations as trial sites.

The following is information disclosed by VIVE relative to the two pivotal (LIBERATE) studies.

U.S. LIBERATE Study

- Design
  - N=200 w/ mild-to-moderate SUI
  - Randomized, double-blind, sham-controlled
  - Sites = 25, in U.S.
  - Outcomes
    - Primary: 1-hour pad weight test, change from baseline to 12 months
    - Secondary: (undisclosed) "other secondary endpoints"
    - Safety: through 12 months
- Status: VIVE expects to submit IDE to FDA for "temporary improvement of mild-to-moderate SUI"

International LIBERATE Study

- Design
  - N=100 w/ mild-to-moderate SUI
  - Randomized, double-blind, sham-controlled
  - Sites = 10, in Canada
  - Outcomes
    - Primary: 1-hour pad weight test, change from baseline to 6 months
    - Secondary: (undisclosed) "other secondary endpoints"
    - Safety: through 12 months
  - Status: currently in the process of reviewing the protocol with Health Canada
- Purpose: if positive, will use study to support Health Canada registration filing and CE Mark application for "temporary improvement of mild-to-moderate SUI symptoms

HISTORICAL STOCK PRICE



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