



## Healthcare Industry Update

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Wednesday, March 28<sup>th</sup>, 2018



## THE ORIGIN RX

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### Law & Order

The aptly-named 21st Century Cures Act was signed into US law on December 13, 2016 to provide critical tools and resources which advance basic healthcare research and modernize clinical trials. There was strong bipartisan support (remember those days?) for the legislation which boosts funding for medical research, eases the development and approval of experimental treatments and reforms federal policy on mental health care. The handful of dissenters were concerned about dropping the bar for regulatory standards too low and throwing excessive benefits to pharma and device companies, but they were unable to persuade the majority.

The Cures Act provides \$4.8B in new funding to the National Institute of Health (NIH) over 10 years, with \$1.8B reserved for the Cancer Moonshot and \$1.6B directed toward brain diseases like Alzheimer's. It also includes \$0.5B in new funds for the US Food and Drug Administration (FDA) and \$1B in grants to help states deal with opioid abuse.

Reforms now enable researchers to “learn while doing,” without having to wait until a clinical trial is done before taking the next step. Researchers developing treatments for very rare diseases will be able to make use of alternate statistical analyses in order to demonstrate statistically significant outcomes from relatively small patient numbers. Approvals of new indications for medicines already in use may be expedited by the use of real-world data.

**CROs respond:** Contract research organizations (CROs) are positioning for increasing demand for real-world data to support regulatory filings. Recognizing that clinical trial data may prove a drug's efficacy, but it could take real-world data to demonstrate its value, a number of large CROs are doubling down on this capability in the wake of the Cures Act. **Parexel** set up a team to provide real-world data insights to “allow clients to more seamlessly collect and communicate the specific data that payers, physicians, and patients require to establish that a new product offers greater benefits than the existing standard of care.” **PPD** combined its medical affairs research operations with Evidera, the provider of evidence-based solutions to demonstrate real-world effectiveness, safety and value of biopharmaceutical and biotechnology products that PPD acquired in 2016.

And just last week, **Worldwide Clinical Trials** announced the acquisition of **Continuum Clinical's** Late Stage research practice to add to its Evidence business unit. According to Worldwide, the acquisition will expand its observational research study services, as well as add health economics services, patient-reported outcomes research and patient registries, among other real-world initiatives on both the pre- and post-approval sides.

**Oh Canada?** According to 2013 research by the Fraser Institute, Health Canada's Therapeutic Products Directorate lagged behind its EU counterparts and the FDA. The gap is expected to widen as a result of the Cures Act, intended to accelerate the discovery, development and delivery of 21st-century cures. With the goal of saving lives, the ultimate success of the Cures Act in getting new treatments and devices to patients in the US is still largely to be determined. But I'm guessing we'll study it.

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CATHY STEINER, PRINCIPAL





## BIGGEST MOVERS

### Recent News<sup>1</sup>

Markets have struggled in the second half of March, with the TSX decreasing 2.9% and the Nasdaq decreasing 6.3%. It's been a mixed bag in healthcare subsectors, which follow in this report. A selection of the largest share price movers in the healthcare space during the recent period is included below:

- **CASI Pharmaceuticals, Inc.** (NasdaqCM:CASI, **+23%**): CASI Pharmaceuticals is a late-stage biopharmaceutical company focusing on therapeutics addressing cancer treatment in China. Strong recent share performance was driven by the company's announcement of its US\$50 million private placement, that it will use to prepare its first commercial product launch in China
- **Arena Pharmaceuticals, Inc.** (NasdaqGS:ARNA, **+23%**): Arena Pharmaceuticals is a biopharmaceutical company focusing on developing novel small molecule drugs for various therapeutic areas in the United States and Switzerland. Shares performed well of late due to the announcement that the company's Phase 2 OASIS drug trial for Etrasimod in patients with Ulcerative Colitis met primary and all secondary endpoints
- **Vital Therapies, Inc.** (NasdaqGS:VTL **+16%**): Vital Therapies is a biotherapeutic company focusing on developing and commercializing a cell-based therapy for the treatment of acute forms of liver failure in the United States. Strong share performance was driven by the company's announcement that its VTL-308 phase 3 trial reached its enrollment target of 150 subjects
- **Fennec Pharmaceuticals Inc.** (NasdaqCM:FENC, **+14%**): Fennec Pharmaceuticals is a biopharmaceutical company developing product candidates for use in the treatment of cancer in the United States. Strong recent performance has been driven by the announcement that the FDA granted the company's PEDMARK formulation Fast Track designation for prevention of cisplatin-related ototoxicity in pediatric patients with standard risk hepatoblastoma. There are currently no drugs approved in the US for this condition
- **Alder Biopharmaceuticals, Inc.** (NasdaqGM:ALDR, **-16%**): Alder Biopharmaceuticals is a clinical-stage biopharmaceutical company that develops therapeutic antibodies for the treatment of migraines and other neurological conditions. The recent share price decline has been driven by the company's announcement that CEO Randall Schatzman will be leaving his role, just months before the firm is expected to ask US regulators to approve a key migraine drug, eptinezumab
- **AbbVie Inc.** (NYSE:ABBV, **-18%**): AbbVie discovers, develops, manufactures and sells pharmaceutical products worldwide. Share prices recently fell after the company announced it would not apply for accelerated regulatory approval for Rova-T, a small cell lung cancer drug it acquired when it bought biotech start-up Stemcentrx in a deal worth up to US\$10 billion nearly two years ago

Note 1: For the period March 15<sup>th</sup> to March 27<sup>th</sup>, 2018



## US HEALTHCARE WATCHLIST

### News Scan<sup>1</sup>

- The US Healthcare Watchlist index lost approximately 9% over the last twelve months, while the TSX Composite Index lost 1% over the same period. Some events making news this month:
- On Mar. 20<sup>th</sup>, **Prothena Corporation PLC**, a late-stage clinical biotechnology company focusing on novel immunotherapies for the treatment of diseases in the neuroscience and orphan categories, announced a global collaboration with **Celgene Corporation** to develop new therapies for a broad range of neurodegenerative diseases. Under the terms of the collaboration, Prothena will receive a US\$100 million upfront payment and a US\$50 million equity investment by Celgene, and Celgene will have exclusive rights to license the clinical candidates in the US
- On Mar. 15<sup>th</sup>, **Worldwide Clinical Trials, Inc.**, a global full-service contract research organization, announced it acquired the Late Stage research practice of **Continuum Clinical, LLC** located in Northbrook, Illinois, for an undisclosed amount. Seasoned veterans from Continuum's Late Stage research practice will join the Worldwide Evidence business unit, expanding Worldwide's observational research study services and adding health economics services, patient-reported outcomes research, patient registries, and other pre- and post-approval initiatives designed to generate real-world data
- On Mar. 23<sup>rd</sup>, **GlaxoSmithKline PLC** announced it will no longer pursue the acquisition of **Pfizer's** consumer health-care business, which was expected to cost as much as US\$20 billion for brands including Advil, Centrum and Chapstick. GSK shares rose 3% following the announcement, as investors' concerns about a potential dividend cut eased
- On Mar. 16<sup>th</sup>, **Johnson & Johnson** announced it received a binding offer from **Platinum Equity** to acquire its **LifeScan** business for approximately US\$2.1 billion. LifeScan, Inc. is a leader in blood glucose monitoring products with 2017 net revenue of approximately US\$1.5 billion. Johnson & Johnson executive Ashely McEvoy stated the company is confident that the business would have a promising future with Platinum Equity. If the offer is accepted, the transaction would be expected to close by the end of 2018, subject to the satisfaction of customary closing conditions
- On Mar. 27<sup>th</sup>, **GlaxoSmithKline PLC** announced it reached an agreement with **Novartis** to buyout Novartis' 36.5% stake in the Consumer Healthcare Joint Venture between the two companies, for approximately US\$13 billion. The transaction is expected to be accretive to adjusted earnings in 2018 and thereafter, and to strengthen cash flow generation. GSK has entered into a committed facilities agreement to support funding of the buyout

### Relative Performance Index



Note 1: For the period March 15<sup>th</sup> to March 27<sup>th</sup>, 2018

**US Healthcare Watchlist Constituents:** Johnson & Johnson, Pfizer Inc., Roche Holding AG, Novartis AG, Merck & Co., Inc., AbbVie Inc., Amgen Inc., Medtronic plc, Gilead Sciences, Inc., Bayer AG, Abbott Laboratories, Bristol-Myers Squibb, GlaxoSmithKline plc, Eli Lilly and Company, AstraZeneca PLC, Celgene Corporation, Allergan plc, Boston Scientific Corporation, Mylan N.V., Teva Pharmaceutical Industries, Mallinckrodt Public Limited Company, Endo International plc

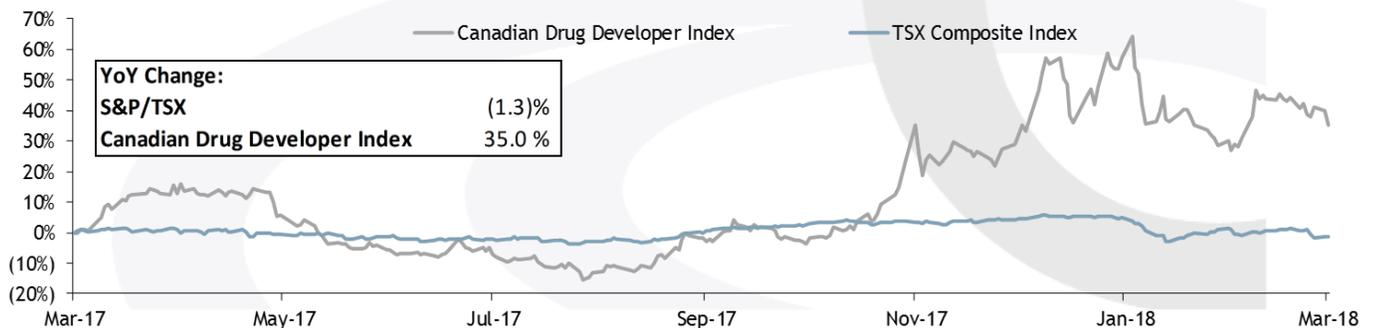


## CANADIAN DRUG DEVELOPERS

### News Scan<sup>1</sup>

- Last twelve-month performance of the Canadian Drug Developer index was an impressive 35%, significantly outperforming the TSX Composite Index which lost 1% over the same period. In the news this month:
- On Mar. 22<sup>nd</sup>, **Cardiome Pharma Corp.**, a specialty pharmaceutical company engaging in the development and commercialization of therapies for the treatment of patients suffering from heart diseases, announced Health Canada accepted its New Drug Submission for review of Xibalba and granted Priority Review status to the application. Cardiome expects to receive an approval decision for Xydalba during the third quarter of 2018
- On Mar. 20<sup>th</sup>, **Cipher Pharmaceuticals Inc.** announced it will acquire the Canadian business portfolio of **Cardiome Pharma Corp.**, for approximately C\$25.5 million. The portfolio includes commercial and pipeline hospital products administered in the acute care setting, including Brinavess, Aggrastat and Xydalba. Pursuant to the arrangement, Cardiome shareholders will receive common shares, on a one-for-one ratio, of a newly created Canadian entity named **Correvio Pharma Corp.** that will apply for a substitution listing on the Nasdaq and TSX
- On Mar. 16<sup>th</sup>, **Tetra Bio-Pharma Inc.** announced it is conducting a non-brokered private placement of up to 4.5 million units at a price of \$1 per unit, for aggregate gross proceeds of up to \$4.5 million. Each unit consists of one common share and one warrant with an exercise price of C\$1.30 and 36-month maturity. The company intends to use the net proceeds of the offering to advance Phase 3 trials for PPP001 and other clinical trials
- On Mar. 14<sup>th</sup>, **Zymeworks Inc.** announced that ZW49 is the first product candidate selected for clinical development utilizing the ZymeLink antibody-drug conjugate platform, acquired as part of the company's 2016 acquisition of **Kairos Therapeutics**. The company expects to file an Investigational New Drug application this year in order to begin clinical trials with ZW49 for patients with HER2-expressing cancers

### Relative Performance Index



Note 1: For the period March 15<sup>th</sup> to March 27<sup>th</sup>, 2018

**Canadian Drug Developers Constituents:** ProMetic Life Sciences Inc., Clementia Pharmaceuticals Inc., Aurinia, Pharmaceuticals Inc., Arbutus Biopharma Corporation, Resverlogix Corp., Aquinox Pharmaceuticals, Inc., Zymeworks Inc., ImmunoVaccine Inc., InMed Pharmaceuticals Inc., Sierra Oncology, Inc., Tetra Bio-Pharma Inc., Oncolytics Biotech Inc., Cardiome Pharma Corp., Acerus, Pharmaceuticals Corporation, ProMIS Neurosciences Inc., Aeterna Zentaris Inc., Trillium Therapeutics Inc.

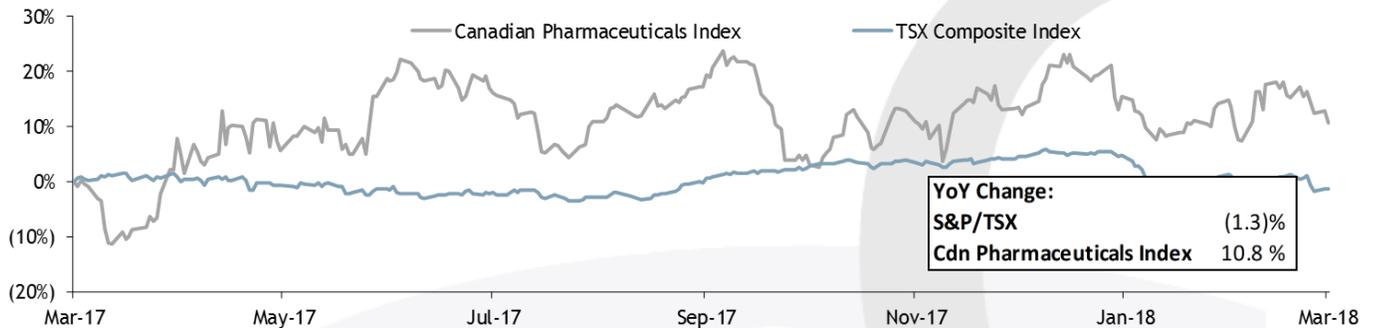


## CANADIAN PHARMACEUTICALS

### News Scan<sup>1</sup>

- The Canadian Pharmaceutical index gained approximately 11% over the last twelve months, beating the TSX Composite Index which lost 1% over the same period. News for Canadian-listed pharmaceutical companies in March 2018:
- On Mar. 19<sup>th</sup>, **Ardelyx, Inc.** announced it has entered into a licensing agreement with **Knight Therapeutics, Inc.** that provides Knight with exclusive rights to commercialize Tenapanor, Ardelyx's oral small molecule treatment for irritable bowel syndrome, in Canada. Under the terms of the agreement, Ardelyx is eligible to receive up to C\$25 million in total payments including an upfront payment and development and sales milestones, as well as double-digit tiered royalties on net sales
- On Mar. 26<sup>th</sup>, **Valeant Canada** announced Health Canada approved CONTRAVE extended-release tablets for use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults. CONTRAVE was approved by the US FDA in 2014, and has now been approved for sale in 25 countries

### Relative Performance Index



Note 1: For the period March 15<sup>th</sup> to March 27<sup>th</sup>, 2018

**Canadian Pharmaceuticals Constituents:** Valeant Pharmaceuticals International, Inc., Knight Therapeutics Inc., Concordia International Corp., Arelz Pharmaceuticals Inc., Theratechnologies Inc., Zomedica Pharmaceuticals Corp.

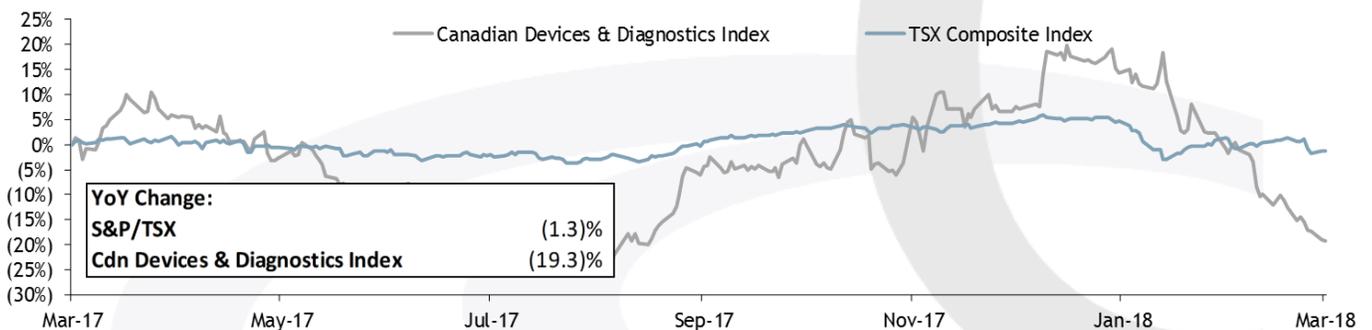


## CANADIAN DEVICES & DIAGNOSTICS

### News Scan<sup>1</sup>

- The Canadian Devices & Diagnostics index lost approximately 19% over the last twelve months, lagging the TSX Composite Index which lost 1% over the same period. Newsmakers for March 2018:
- On Mar. 14<sup>th</sup>, **TSO3 Inc.**, a developer of sterilization technology for medical devices in healthcare settings, announced it received 510(k) clearance from US regulators for a significant improvement to its STERIZONE VP4 Sterillizer device. The device is a low-temperature sterilization system that utilizes vaporized hydrogen peroxide and ozone to achieve terminal sterilization of heat and moisture sensitive medical devices. The cleared change can improve the customer installation process and reduce start-up costs by significantly reducing the oxygen supply requirements for the system
- On Mar. 19<sup>th</sup>, **Spectral Medical Inc.**, a Phase III company developing the first targeted treatment for patients with septic shock, announced the FDA determined more evidence is required to make the final determination to approve its PMX cartridge. The FDA acknowledged the unmet need for therapies in septic shock patients who face a high risk of death, and offered to discuss Spectral's proposal for further data collection in order to develop a mutually agreeable plan
- On Mar. 5<sup>th</sup>, **CRH Medical Corporation**, a company that provides products and services for the treatment of gastrointestinal diseases in the United States, announced that it acquired a gastroenterology anesthesia practice in Shreveport, Louisiana (Shreveport), for an undisclosed amount. Shreveport provides anesthesia services to an ambulatory surgical center and is CRH's first acquisition in the state of Louisiana. The transaction was financed through a combination of CRH's credit facility and cash on hand, and is expected to be accretive to earnings

### Relative Performance Index



Note 1: For the period March 15<sup>th</sup> to March 27<sup>th</sup>, 2018

**Canadian Devices and Diagnostics Constituents:** CRH Medical Corporation, TSO3 Inc., Titan Medical Inc., Opsens Inc., Neovasc Inc., ChromedX Corp., Profound Medical Corp., Covalon Technologies Ltd., Spectral Medical Inc., Hamilton Thorne Ltd.

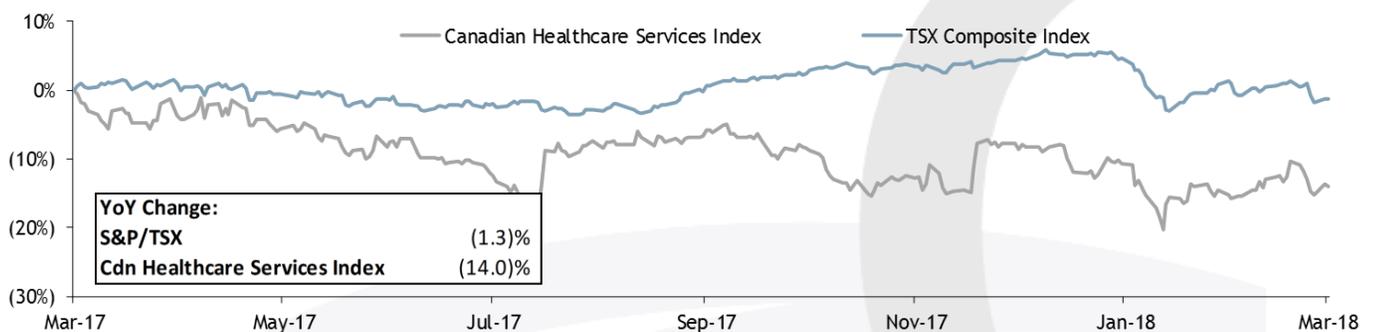


## CANADIAN HEALTHCARE SERVICES

### News Scan<sup>1</sup>

- The Canadian Healthcare Services index experienced a decline of approximately 14% over the last twelve months, lagging the TSX Composite Index which lost 1% over the same period. March 2018 news highlights among the group:
- On Mar. 26<sup>th</sup>, **Akumin Inc.**, a provider of outpatient diagnostic imaging services in the United States, announced that its wholly owned subsidiary, **Preferred Medical Imaging, LLC**, entered into agreements to acquire all of the outstanding non-controlling interests in seven of its existing Texas-based diagnostic imaging centers, for approximately US\$21.3 million. The company expects that having the centers as wholly-owned subsidiaries will further simplify corporate structure and be accretive to EBITDA
- On Mar. 26<sup>th</sup>, **Extendicare Inc.**, a senior care service provider in Canada, announced it reached an agreement with a syndicate of underwriters to issue to the public, on a bought deal basis, C\$110 million aggregate principal amount of 5% convertible unsecured debentures. The net proceeds from the offering will be used to partially fund the redemption of the company's outstanding 6.00% convertible debentures due on September 30, 2019

### Relative Performance Index



Note 1: For the period March 15<sup>th</sup> to March 27<sup>th</sup>, 2018

**Canadian Healthcare Services Constituents:** Sienna Senior Living Inc., Extendicare Inc., Medical Facilities Corporation, Akumin Inc, Centric Health Corporation

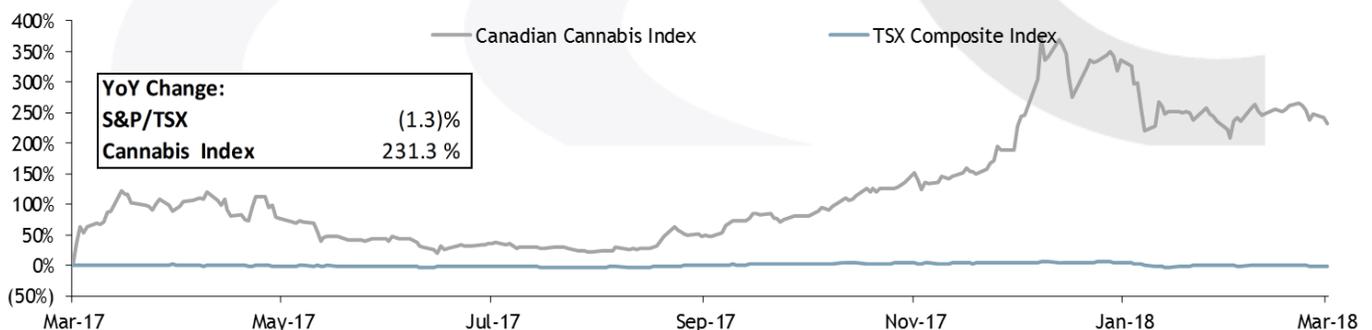


## CANNABIS

### News Scan<sup>1</sup>

- Last twelve-month performance of the Cannabis index was approximately 231%, dwarfing the 1% loss of the TSX Composite Index over the same period. Highlights of cannabis news for March 2018:
- On Mar. 23<sup>rd</sup>, **Aphria Inc.** completed the previously announced acquisition of the remaining 93.5% of **Nuuvera Inc.** for approximately C\$400 million. Under the terms of the agreement, each former Nuuvera shareholder is entitled to receive C\$0.62 in cash plus 0.3546 of a common share of Aphria for each Nuuvera share held. Aphria's initial cash bid for Nuuvera comprised of C\$1 per share, instead of the C\$0.62 agreed upon at closing. Aphria did not expand on the rationale behind the reduced cash offer, but cannabis companies have been experiencing high price volatility in trailing months
- On Mar. 21<sup>st</sup>, **Aphria Inc.** announced it entered into an exclusive supply agreement with an undisclosed Argentinian based pharmaceutical import and distribution company, which is licensed to import, sell and distribute medical products and derivatives in Argentina. The importer is currently securing an import license for cannabis in Argentina. Under the terms of the agreement, Aphria will be the exclusive supplier of cannabis products to the importer for the Argentine market
- On Mar. 19<sup>th</sup>, **MedReleaf** announced it entered into an agreement to become the largest supplier of medical cannabis products to **Cannamedical Pharma GMBH**, a leading medical cannabis distributor to pharmacies in Germany. Sales to Germany will commence promptly upon the expected receipt of MedReleaf's European Medical Agency Good Manufacturing Practices certification and export permit from Health Canada in the coming weeks
- On Mar. 20<sup>th</sup>, **Supreme Cannabis** announced it entered into a definitive agreement to acquire 10% of **Medigrow Lesotho, Ltd.**, a federally licensed producer of cannabis in the Kingdom of Lesotho in Southern Africa, for C\$10 million. Supreme Cannabis expects strong demand to exceed supply for medical cannabis oil globally and believes Lesotho is well suited to produce quality cannabis oil, while Medigrow possesses the expertise to meet the highest quality standards
- On Mar. 27<sup>th</sup>, **CannaRoyalty** announced it acquired **River Distribution**, a cannabis distributor and marketer in California with a variety of brands sourced across the state, for approximately C\$20.6 million. CannaRoyalty also closed the previously announced acquisitions of **Kaya Management Inc.** and **Alta Supply Inc.** for approximately C\$13.6 million. CannaRoyalty will assume the California operations of Kaya and Alta Supply, and hopes the three acquisitions will position the company as a leader in the California cannabis distribution system

### Relative Performance Index



Note 1: For the period March 15<sup>th</sup> to March 27<sup>th</sup>, 2018

**Cannabis Index Constituents:** Canopy Growth Corporation, Aurora Cannabis Inc., Aphria Inc., MedReleaf Corp., CannTrust Holdings Inc., CanniMed Therapeutics Inc., Cannabis Wheaton Income Corp., OrganiGram Holdings Inc., The Supreme Cannabis Company, Inc., The Hydropharmacy Corporation



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