

# Healthcare Industry Update

Monday, September 17<sup>th</sup>, 2018









## THE ORIGIN RX

#### Timing is everything

It was impossible to miss Apple's announcement of two new mobile medical apps to be used with the Apple Watch 4 - ECG software for OTC use and an irregular rhythm notification feature. Timing of FDA clearance could not have been more perfect, just the day before the company's September 12th launch event at the Steve Jobs Theatre.

The ECG app creates, records, stores, transfers, and displays a single channel ECG similar to a Lead I ECG and can determine the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The ECG recordings are then stored in the Health app and can be shared with physicians. The ECG app is not recommended for users with other known arrhythmias or for individuals under 22 years old.

The irregular rhythm notification app analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of AFib and provides a notification to the user. The notification feature can be used to supplement the decision for AFib screening but it is not intended to replace traditional methods of diagnosis or treatment. It is also not intended for use in those under 22 years old or in patients previously diagnosed with AFib.

The FDA is not generally famous for moving rapidly, but they sure moved at lightning speed on this file. Apple began recruiting patients in November of last year, submitted its applications mid-August and received FDA clearance on September 11th, 2018. This was a de novo submission - the FDA's goal for de novo submissions is to issue a decision within 150 days of receipt - so I'm guessing FDA clearance in less than 30 days is a new record.

The Apple Heart Study, conducted in partnership with Stanford Medicine, looked at 588 individuals, half with AFib and the other half with healthy heart rates. The app was able to identify over 98% of subjects with AF and over 99% with healthy heart rates. Data collection will continue to January 31, 2019. In order to mitigate risk, the FDA requires Apple to notify users of its ECG software of the risks in faulty arrhythmia detection and the dangers of misinterpretation or over-reliance on the software.

In a statement from FDA Commissioner Scott Gottlieb and Center for Devices and Radiological Health Director Jeff Shuren, the FDA worked closely with Apple as they developed and tested these software products. They acknowledge that health care has been slow to implement disruptive tech tools that have been successfully transforming other areas of business and daily life, ranging from ride-hailing apps and virtual home assistants to fin tech and food delivery - and the complex regulatory framework has likely played a part. While always putting patient protection at the forefront, they intend to take a regulatory approach that fosters innovation, rather than inhibits it. This means they plan to reduce the time and cost of market entry, while assuring necessary patient safeguards are in place. Hopefully this is the mantra for all and not just Apple.

Since we're on the topic of timing, it's hard to miss the fact that we're in the final month before legalization of rec can be use in Canada. There is a flurry of discussions, plans and rumours, and stocks are up. We should have more on that in two weeks...

CATHY STEINER, PRINCIPAL











## **BIGGEST MOVERS**

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

Markets have been relatively flat in the last two weeks with the TSX decreasing 2.0% and the NASDAQ increasing by 1.8%. 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:

- Liberty Health Sciences Inc. (CNSX:LHS +103%); Liberty Health Sciences is a producer and distributor of medical cannabis in the State of Florida. Recent share price appreciation was due to an announcement that Liberty has received approval to manufacture and dispense Solei Sungrown Cannabis products in Florida. Furthermore, they received approval from the Florida Department of Health to implement the state's first online patient management system, called FlorPass
- WeedMD, Inc. (TSXV:WMD +68%): WeedMD produces and sells medical marijuana in Canada. Recent share price increase was mainly due to its announced supply agreement with the Ontario Cannabis Retail Corporation as well as the completion of its first harvest at its state-of-the-art greenhouse
- Synlogic, Inc. (NasdagGM:SYBX +67%): Synlogic is a clinical-stage biopharmaceutical company focusing on the discovery and development of synthetic biotic medicines to treat metabolic, inflammatory, and cancer diseases. The recent increase in its share price is primarily due to an announcement of positive interim clinical data from its ongoing phase 1/2a study of SYNB1618 in patients with Phenylketonuria (PKU)
- MannKind Corporation (NasdagGM:MNKD +62%): MannKind is a biopharmaceutical company focusing on the development and commercialization of inhaled therapeutic products for diabetes and pulmonary arterial hypertension patients. Recent share price appreciation was largely due to the announcement that MannKind has entered into an exclusive license agreement for the development and commercialization of Treprostinil, a product being evaluated for the treatment of pulmonary arterial hypertension
- Vital Therapies, Inc. (NasdaqGS:VTL -26%): Vital Therapies is a biotherapeutic company that focuses on developing and commercializing cell-based therapy for the treatment of acute forms of liver failure. Recent share price decline is due to the announcement that the VTL-308 study failed to achieve the primary and secondary endpoints of improvement in survival
- Lannett Company, Inc. (NYSE:LCI -59%): Lannett develops and manufactures generic versions of brand pharmaceuticals. Share prices declined significantly after Rosen Law Firm announced the filing of a class action lawsuit on behalf of the shareholders of the company. According to the lawsuit, defendants failed to disclose that Lannett faced a substantial risk of the loss of its exclusivity agreement with Jerome Stevens Pharmaceuticals

Note 1: For the period August 15th to September 14th, 2018







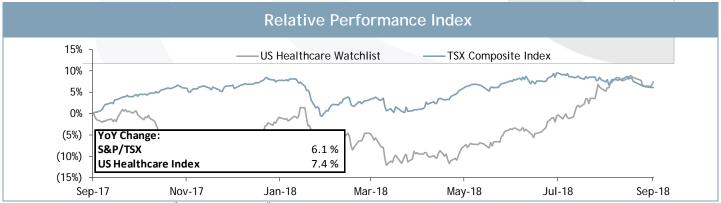




# **US HEALTHCARE WATCHLIST**

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

- The US Healthcare Watchlist Index gained approximately 7.4% over the last twelve months, while the TSX Composite Index gained 6.1% over the same period. Some events making news this month:
- On September 13<sup>th</sup>, <u>Roche</u> announced it will be cutting costs in an effort to compete against cut-price biosimilars for Rituxan, Avastin and Herceptin. The company has recently cut 223 jobs from Genentech's headquarter aimed to streamline its global business unit. Roche estimates it could have a sales gap of \$10 billion by 2022
- On September 12<sup>th</sup>, <u>Bristol-Meyers Squibb</u> announced positive efficacy results of a Phase II study of its oral selective tyrosine-kinase-2 inhibitor to treat moderate to severe forms of plaque psoriasis. Bristol-Myers relies heavily on a blockbuster cancer drug, and this will diversify their portfolio
- On September 12<sup>th</sup>, German drug maker <u>Bayer</u> announced it will be adding warning labels on its prescription-free stomach relief drops after it was linked to rare cases of liver damage. The treatment, originally introduced in 1960 has approval in more than 40 countries, and has been used by 82 million patients
- On September 12<sup>th</sup>, <u>Gilead Sciences</u> announced its collaboration with <u>Precious BioSciences</u> to develop a treatment aimed to eliminate Hepatitis B Virus (HBV) through the use of Precision's gene editing platform ARCUS. Precision will be leading the development, while Gilead will be responsible for the clinical development and commercialization of the treatment. The partnership is expected to generate \$445 million for Precision
- On September 10<sup>th</sup>, <u>Urovant Sciences</u>, a biopharmaceutical company focused on treatments for urologic conditions, filed for its initial public offering of a proposed maximum of \$150 million, which will be led by JP Morgan, Jefferies and Cowen. Urovant will be listed on the Nasdag under the symbol UROV
- On September 10<sup>th</sup>, <u>Carlyle Group</u> announced it will acquire a significant minority stake in <u>Ambio Holdings Inc.</u>, also known as AmbioPharm. Ambio is a predominantly North American pharmaceutical company that manufactures peptide active ingredients at facilities both in the U.S. and China
- On September 6<sup>th</sup>, <u>Boston Scientific</u> agreed to acquire <u>Augmenix</u>, a privately held healthcare equipment producer for US\$600 million. Augmenix is behind the development of SpaceOAR System which is used to reduce side effects in men with prostate cancer who've received radio therapy
- On August 31<sup>st</sup>, <u>HCA Healthcare</u>, a healthcare service company, announced it has agreed to purchase <u>Mission Health</u>, a non-profit health system for US\$1.5 billion. The acquisition includes seven of Mission Health's locations in North Carolina
- On August 17<sup>th</sup>, Entasis Therapeutics, a clinical-stage biopharmaceutical company, filed for an initial public offering for a maximum of \$86 million, which will be led by Credit Suisse and BMO Capital Markets, along with SunTrust Robinson Humphrey and Wedbush PacGrow



Note 1: For the period August 15th to September 14th, 2018

<u>US Healthcare Watchlist Constituents:</u> 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







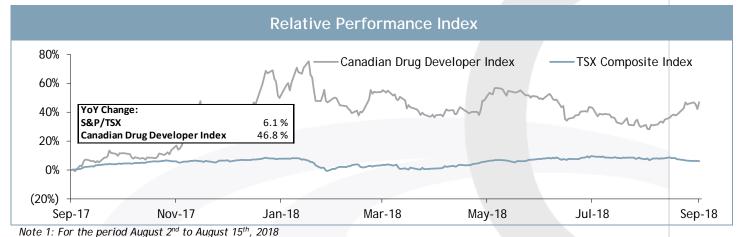




# CANADIAN DRUG DEVELOPERS

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

- Last twelve-month performance of the Canadian Drug Developers Index was an impressive 46.8%, significantly outperforming the TSX Composite Index which only gained 6.1% over the same period. In the news this month:
- On September 6<sup>th</sup>, Oncolytics Biotech announced it has entered into a Master Clinical Supply agreement with Hoffman-La Roche Ltd to supply Tecentric<sup>TM</sup> for the company's clinical development program. The agreement aims to investigate Reolysin's<sup>TM</sup> impact on cancer treatments used in conjunction with Tecentric<sup>TM</sup>
- On September 5th, Tetra Bio-Pharma announced that it has secured a competitive CBD supply agreement with True North Cannabis in order to develop a cannabinoid derived oral capsule as well as a topical cream to treat joint pain and inflammation. The development of this topical treatment is in partnership with Genacol
  - On August 14th, Tetra announced the completion of a development and commercialization agreement with Genacol Canada Corporation. Genacol will be responsible for the promotion and sales of the product throughout Canada, which represents a \$2.5 billion market. The product is expected to launch in 2019
- On August 30th, Resverlogix Corporation, a Canadian developmental stage biotechnology company, announced it has closed a private placement of approximately C\$10.4 million in equity units at a price of \$2.50 per unit with gross proceeds of C\$26 million



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.





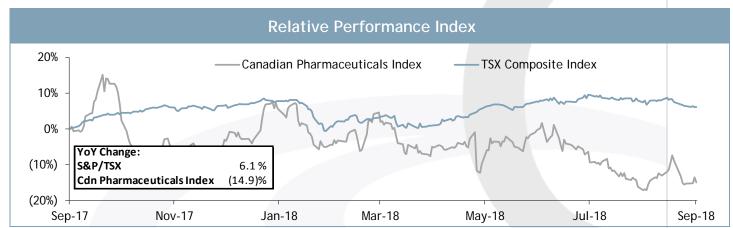




# CANADIAN PHARMACEUTICALS

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

- The Canadian Pharmaceuticals Index experienced a decline of approximately 14.9% over the last twelve months, while the TSX Composite Index gained 6.1% over the same period. Recent news highlights include:
- On September 11th, Concordia International, a specialty pharmaceutical company, announced the completion of a private placement financing, raising a total of C\$587 million at \$13.69 per share. The transaction is completed for recapitalization purposes of its \$1.6 billion in unsecured debt for the new limited voting shares that represents approximately 12% of outstanding voting rights
- On September 11th, Bausch Health Companies Inc. announced it paid down \$57 million of its senior secured term loans and \$50 million of its revolver borrowings with cash. This repayment adds to the additional \$132 million pay down from Q3 this year in an effort to eliminate mandatory amortization for fiscal year 2018
  - On September 5th, Bausch released phase 3 clinical trial results for its loteprednol etabonate ophalmic gel, a treatment of postoperative pain and inflation treatment for eyes. The treatment met both safety and efficacy endpoints, with expectations of FDA approval in early 2019
  - On August 29th, FDA announced it has accepted the review of Bausch's refiled application of its Ortho Dermatologics' topic treatment called the DUOBRII. The FDA has up till February 15, 2019 for further consideration. The treatment's original application was scrutinized for its pharmacokinetics, which is the drug absorption, distribution and metabolism ability in the human body



Note 1: For the period August 2<sup>nd</sup> to August 15<sup>th</sup>, 2018

Canadian Pharmaceuticals Constituents: Bausch Health Companies Inc., Knight Therapeutics Inc., Concordia International Corp., Aralez Pharmaceuticals Inc., Theratechnologies Inc., Zomedica Pharmaceuticals Corp.





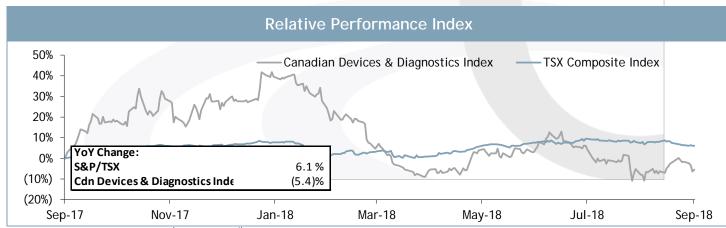




## CANADIAN DEVICES & DIAGNOSTICS

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

- The Canadian Devices & Diagnostics Index lost approximately 5.4% over the last twelve months, lagging the TSX Composite Index which gained 6.1% over the same period. Newsmakers for September 2018:
- On September 14th, Hamilton Thorne Ltd., a developer and manufacturer of precision laser devices and advanced image analysis systems, announced that it has completed of a bought deal private placement for aggregate proceeds of C\$10mm. The offering was led by Bloom Burton Securities with proceeds to be earmarked for future acquisitions and general working capital
- On September 11th, Neovasc Inc., a specialty medical device company that develops and manufactures products for the cardiovascular marketplace, was made aware of a lawsuit filed by Endovalve Inc. and Micro Interventional Devices, Inc. The complaint has not yet been served on the Company but it is related to its transcatheter mitral valve
- On September 4<sup>th</sup>, CRH Medical Corporation, a products and service provider to gastroenterologists, announced the acquisition of Lake Erie Sedation Associates for an undisclosed sum. Lake Erie's affiliated physicians are existing customers of CRH and the company looks forward to continue to leverage the strength of those relationships
- On August 28th, Titan Medical Inc., a medical device company focused on the design and development of a robotic surgical system for application in minimally invasive surgery (MIS), announced that it has been given a patent covering technology that advances the ease of use and positioning of robotic surgical systems, such as Titan's SPORT Surgical System. The patent will further enhance Titan's intellectual property position in single-port robotic surgery
- On August 23rd, Relay Medical Corp., a medical technology company focusing on the development of Vitro diagnostics and point-of-care technologies, announced it has signed a term sheet to acquire a gynecological clinical invention that is aimed to address gynecological complications. Under the terms of the deal, the company will own 85% of a new subsidiary
- On August 20th, TSO<sub>3</sub> Inc., a producer of medical sterilizers, announced that UCHealth has performed the first patient procedure in Colorado using TSO's Sterizone technology. The procedure involved the use of a duodenoscope, which is used to take images of the patient's liver and gall bladder. The device was sterilized using Sterizone technology



Note 1: For the period August 2<sup>nd</sup> to August 15<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.





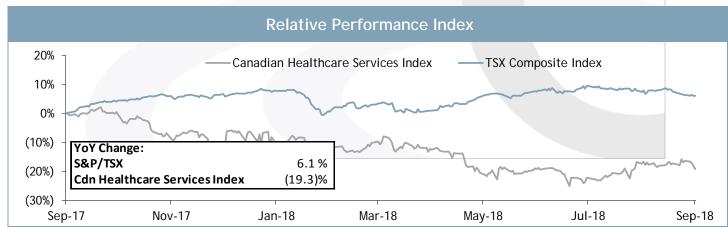




## CANADIAN HEALTHCARE SERVICES

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

- Last twelve-month performance of the Canadian Healthcare Services Index decreased 19.4%, while the TSX Composite Index increased 6.1% over the same period. In August, the following occurred in the Canadian healthcare services space:
- On September 10th, Centric Health Corporation, a healthcare services company that operates specialty pharmacy and surgical medical centres, announced that it has been awarded a new contract to service 900 new beds with a multi-regional operator. The company now expects to service approximately 31,0000 beds by the end of 2018, representing an 8% increase since June 30, 2018
  - On September 5<sup>th</sup>, Centric Health Corporation announced that it had entered into a multi-year supply and service agreement with Canopy Growth Corporation for the provision of medical cannabis. Under the agreement, Canopy will be the preferred education partner and supplier of choice of medical cannabis primarily through its Spectrum Cannabis brand
- On September 7<sup>th</sup>, Ascent Industries Corp., a licensed producer under the Access to Cannabis for Medical Purposes Regulations of Health Canada, announced that it has entered into a supply agreement with the Ontario Cannabis Retail Corporation, operating as the Ontario Cannabis Store ("OCS"), to supply branded cannabis products to the adult-use market. Under the terms of the agreement, Ascent will supply cannabis products for the OCS's online sales network, and will later supply Ontario's private retailers once the province implements an approved framework
- On September 5<sup>th</sup>, AlayaCare Inc., a provider of home healthcare software solutions, announced that it has entered into a partnership agreement with <u>ComOps Limited</u> to strengthen its presence in the Australian and New Zealand aged care sector. Under the partnership, AlayaCare will re-sell ComOps' market-leading rules interpretation software to home and community care employers
- On August 30th, Medical Facilities Corporation, an owner-operator of specialty surgical hospitals and an ambulatory surgery centre, has announced that it has entered into an agreement for a new US\$150mm syndicated revolving credit facility. The credit facility has a 5-year maturity and replaces the company's current C\$100mm facility that was due to mature at the end of 2018. The CEO commented that the new financing will help them increase flexibility as they focus on building scale and diversifying through accretive acquisitions



Note 1: For the period August 2<sup>nd</sup> to August 15<sup>th</sup>, 2018

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







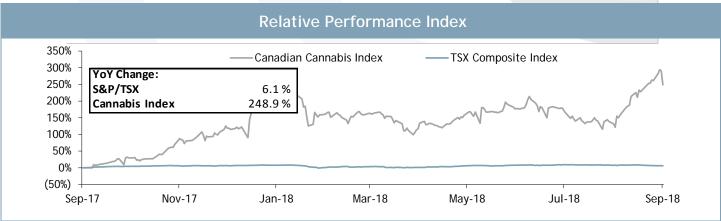




## **CANNABIS**

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

- With 1 month until legalization, the ACMPR has issued 117 licenses. Last twelve-month performance of the Cannabis index was 248.9%, dwarfing the 6.1% gain of the TSX Composite Index over the same period. News highlights:
- On September 12<sup>th</sup>, <u>Aurora Cannabis Inc.</u> announced that it has acquired <u>Agropro UAB</u>, Europe's largest producer of certified organic hemp products, as well as hemp processor <u>Borela UAB</u> for a total consideration of C\$14.9mm. Aurora plans on further developing hemp biomass into CBD-based wellness products to generate new revenue streams for the company
  - On September 10<sup>th</sup>, <u>Aurora Cannabis Inc.</u> announced that it has entered into an agreement to acquire <u>ICC Labs Inc.</u>, for C\$290mm. The acquisition of ICC Labs will establish Aurora as the industry leader in South America
- On September 12<sup>th</sup>, <u>Aphria Inc.</u> announced that it has entered into a wholesale supply agreement with <u>Emblem Cannabis Corporation</u> wherein Aphria will supply 175,000kg of high-quality cannabis over a 5-year period starting in May 2019. Under the terms of the agreement, Aphria will receive a non-refundable deposit of C\$22.8mm, which consists of C\$12.8mm in cash and 6.9mm common shares of Emblem
  - On September 6<sup>th</sup>, <u>Aphria Inc.</u> announced that it has sold its entire investment, some 64.1mm shares, of <u>Liberty Health Sciences Inc.</u> to a consortium of investors, including the Serruya Family. As a result of the transaction, Aphria has divested its remaining U.S. Cannabis assets from its balance sheet in accordance with TSX requirements
- On September 10<sup>th</sup>, <u>CannTrust Holdings Inc.</u> announced that it has entered into an exclusive partnership with <u>Breakthru Beverage Group</u>, the largest Canadian beverage alcohol broker, to develop a route-to-market platform for CannTrust in Canada. The platform is to be effective when the recreational, adult-use market opens in Canada on October 17<sup>th</sup>
- On September 5<sup>th</sup>, <u>Canopy Growth Corporation</u> announced the closing of Canopy's acquisition of <u>Hiku Brands Ltd.</u> For -C\$290mm. The announcement follows a special meeting of Hiku's shareholders where holders of the common shares voted to approve the transaction. As a result, Hiku is now a wholly-owned subsidiary of Canopy and its shares were de-listed from the <u>Canadian Securities Exchange</u> on September 6<sup>th</sup>
  - On August 21<sup>st</sup>, <u>Canopy Growth Corporation</u> announced that it has received amended licenses from <u>Health Canada</u> that increase the size and sophistication of its national footprint. The amended licences include a near doubling of growing capacity and a licence for a highly automated distribution centre at its Smiths Falls Campus as well as an additional 223,000 sq. ft. of cultivation space at its majority-owned <u>Les Serres Vert Cannabis Inc.</u> greenhouse in Mirabel, Quebec
  - On August 20<sup>th</sup>, <u>Canopy Growth Corporation</u> announced that it has been selected as an approved supplier by the <u>Ontario Cannabis Store</u> ("OCS") to supply a wide variety of cannabis products through its online store starting October 17<sup>th</sup>, 2018
- On August 21st, <u>Auxly Cannabis Group Inc.</u> announced that it has entered into an agreement to purchase <u>KGK Science Inc.</u> for total consideration of C\$12.3mm in cash and shares. Auxly expects to leverage KGK's research expertise to further its product development efforts



Note 1: For the period August 2<sup>nd</sup> to August 15<sup>th</sup>, 2018
<u>Cannabis Index Constituents:</u> Canopy Growth, Aurora Cannabis, Aphria, CannTrust Holding, Auxly Cannabis Group, OrganiGram Holdings, The Supreme Cannabis Company, The Hydropothecary



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