Stunning Potential for Upside in Canadian Biotech: Brian Bloom

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COMPANIES MENTIONED

- Alexion Pharmaceuticals Inc.
- **BELLUS Health Inc.**
- Celgene Corp.
- Concordia Healthcare Corp.
- Endo Pharmaceuticals Inc.
- Merus Labs Inc.
- Tekmira Pharmaceuticals Inc.
- **Tribute Pharmaceuticals Canada Inc.**
- Trillium Therapeutics Inc.

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THE ENERGY REPORT
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You may not have thought to look northward for biotech innovators, but Bloom Burton & Co. cofounder and President Brian Bloom can show you some truly hot Canadian companies with compelling skill sets and pipelines. In this interview with *The Life Sciences Report*, Bloom talks about his firm's upcoming conference and presents a detailed picture of four very interesting companies that could return doubles, triples or more.

Source: George S. Mack of *The Life Sciences Report*

***The Life Sciences Report*:** Does your firm perform any buyside activities, or are you strictly a sellside organization performing investment banking, advisory and research functions?

Brian Bloom: We offer a fully integrated platform of services that work together to capitalize, advise and grow extraordinary healthcare companies, and we operate almost exclusively in the Canadian space. We have many different services, including capital raising, merger and acquisition, advisory, equity research, scientific, clinical and medical consulting, company formation, which is a merchant banking function and, finally, direct investments.

We've brought this model to Canada. We may be unique in that we work not just with companies and investors, but we also perform advisory services to a lot of academic organizations in their work in starting up companies, and additionally with building companies from scratch.

TLSR: Your third annual Bloom Burton & Co. Healthcare Investor Conference is June 17–18. Do you have a theme for the conference?

BB: The theme is simply to find the best companies in Canada, where we have a universe of about 120–140 publicly listed companies, most of which are on the Toronto Stock Exchange (TSX) and some of which are also on NASDAQ. There are also hundreds of private life sciences companies here in Canada. We try to choose the best 45 or so companies to showcase to global investors who come to Toronto.

It's a myth that there are lots of great companies and no capital. A lot of capital is out there, and partners like Bloom Burton & Co. can help curate a list of the highest quality companies. That is the purpose of this investor conference.

TLSR: With your proximity to the U.S., I'm wondering how much interest and support you get from Wall Street.

BB: The majority of our attendees are Canadian, but we have a lot of interest and attendance from healthcare specialist investors who travel from New York, Boston, San Francisco and Europe. We often reach out to, and have lead orders for our transactions from, American healthcare specialist investors, including venture capital, hedge funds and private equity investors or lenders. Historically, these firms

drive most of our transactions, and it's the Canadians who generally follow, because they don't have that expertise in the life science sector.

> *"**Tribute Pharmaceuticals Canada Inc.** is my favorite specialty pharmaceutical company right now, based on its valuation."*

Canada is interesting in that we have a long history of risk investing, or investing in small-cap companies. The world comes to Canada for mining, oil and gas, and other natural resource plays because we are the leaders in growth capital and risk capital in that sector. But, the United States—namely Boston, New York and San Francisco—is where the world goes for risk capital in life sciences.

TLSR: Because of their experience with resource investing, Canadian investors are not risk averse?

BB: Yes, but with a caveat. Biotechnology companies are incredibly risky investments. Canadians are very comfortable with risky investments, but have had a long history of losing lots of money in biotechnology because of their lack of expertise in the sector, or lack of understanding the nature and timing of the risks associated with investing in the sector. As you know, biotech is probably the riskiest sector to invest in. You either have to have a lot of expertise or be crazy to invest in biotechnology. From patent, to scientific, to clinical, to regulatory, to commercial and reimbursement, the risks are extraordinary, and there are only a few thousand investors across a couple of hundred funds in the world who do this kind of investing as specialists.

TLSR: The resource sector is a bit softer now. Could that be moving Canadians more into biotech?

BB: The natural resources markets are softer, and therefore Canadians are looking to put their money into other sectors such as healthcare. It hasn't been into emerging, research-stage biotechnology companies; instead, it has been our commercial-stage healthcare companies, such as Paladin Labs (a unit of Endo Pharmaceuticals Inc. (ENDP:NASDAQ)), Knight Therapeutics Inc. (GUD:TSX; KHTRF:OTCMKTS), Concordia Healthcare Corp. (CXR:TSX), Cipher Pharmaceuticals Inc. (DND:TSX), Tribute Pharmaceuticals Canada Inc. (TRX:TSX.V; TBUFF:OTCQB) and Merus Labs Inc. (MSL:TSE). Those six and others are specialty pharmaceutical companies, smaller versions of U.S.-based Forest Laboratories Inc. (FRX:NYSE), Endo, Auxilium Pharmaceuticals Inc. (AUXL:NASDAQ) and Jazz Pharmaceuticals Plc (JAZZ:NASDAQ), which have commercial-stage sales and marketing organizations and only selectively perform late-stage development work.

American investors have embraced biotechnology and early science and clinical development-stage companies, which has resulted in a very strong IPO window, resulting in billions of dollars being funneled into the biotechnology sector. On the other hand, Canada is experiencing an incredibly strong bull market, but only in specialty pharmaceutical and other commercial sectors.

TLSR: Let's talk stocks. Do you have a top pick?

BB: My top pick happens to be a biotechnology company called Trillium Therapeutics Inc. (TR:TSX), a company that changed its name from Stem Cell Therapeutics on June 2. Trillium operates in the immune-oncology space, one of the keenest areas of interest to both the pharmaceutical and investment industries right now. There are very few pure-play immune oncology companies, given that

most of the research is performed by multinationals such as Bristol-Myers Squibb Co. (BMY:NYSE), AstraZeneca Plc (AZN:NYSE), Merck & Co. Inc. (MRK:NYSE), Roche Holding AG (RHHBY:OTCQX) and others. There are some pure-play smaller companies that have assets involved in immune oncology, namely Celldex Therapeutics Inc. (CLDX:NASDAQ) in the U.S. and Innate Pharma SA (IDD:FKT) in France.

*"We believe **BELLUS Health Inc.** has a higher probability of success in its current Phase 3 Kiacta study."*

Trillium is developing an antibody-like molecule called SIRP■ Fc. It's a soluble ligand dimerized with an Fc region that targets a protein called CD47, which is expressed on the surface of tumor cells. CD47 sends a "do-not-eat-me" signal, thereby protecting tumor cells from phagocytosis by macrophages. Cancers and cancer stem cells specifically express CD47 to evade macrophages, which are central elements of the innate immune system.

Macrophages normally survey tissues in the body for foreign elements such as bacteria and viruses, engulf them and subsequently present antigens to acquire immunity against those invaders. Cancer cells overexpress CD47 to hide from the immune system so they can continue to proliferate and metastasize.

TLSR: Trillium has a couple of Phase 1 assets, yet is treating the preclinial SIRP■ Fc as its lead candidate. Does that mean the company is going to put all its focus into SIRP■ Fc?

BB: We believe that almost all the value and future upside of Trillium is in SIRP■ Fc. From a competitive point of view, there is a scarcity of assets that target CD47. Irving Weissman at Stanford University has received more than $30 million ($30M) in California taxpayer money to explore his anti-CD47 antibody, which will soon enter clinical trials. In addition, Celgene Corp. (CELG:NASDAQ) recently announced a very early-stage antibody program that targets CD47. We believe Trillium is ahead of Celgene on this front and is fast on the heels of the Stanford program—and that Trillium Therapeutics could be in clinical trials with SIRP■ Fc by the middle of 2015.

TLSR: You raised $33M for the company in December 2013. How far will this take Trillium?

BB: Trillium is now fully funded through Phase 1/2 clinical trials, and this is very meaningful. This will allow the company to get Phase 2 data in acute myeloid leukemia (AML) and possibly in other liquid and solid tumor indications.

TLSR: The other preclinical program is an anti-CD200 fully human monoclonal antibody, not a fusion protein like SIRP■ Fc. This antibody acts as an immunosuppressant and is overexpressed in many hematopoietic and even solid tumors. Is this something you are valuing in your models currently, or is it taking a back seat to SIRP■ Fc?

BB: It is definitely taking a back seat. The anti-CD200 asset was discovered at Trillium Therapeutics well before the SIRP■ Fc program, and over the past decade, the target has been the subject of partnerships with big biopharmas. You referred to CD200 as an immunosuppressant, yet CD200 biology is not as straightforward as CD47 biology. The problem here is that it is not inhibitory in all situations, and like many immunological targets, it can be suppressive or activating. When Trillium had this partnered with very large companies, it was not obvious in which disease

indication it might be brought forward.

Alexion Pharmaceuticals Inc. (ALXN:NASDAQ) also owns an anti-CD200 program, and it conducted a Phase 1/2 clinical trial in oncology, but the company seems to have ceased development. CD200 is still waiting for basic biology to catch up to its promise as a target.

TLSR: We won't see SIRP■ Fc in the clinic until mid-2015. What moves this stock for investors?

BB: It will be the migration to a U.S. exchange allowing for much broader exposure to a sophisticated U.S. audience that will understand the importance of Trillium's program. The company is not only completing its investigational new drug-enabling work right now—the chemistry, manufacturing and controls—but it is also dramatically expanding its preclinical program to test SIRP■ Fc in multiple liquid and solid tumor animal models, in combination with other chemotherapeutic and biologic anticancer agents as well as in combination with other immune-oncology agents. The company could be worth manyfold what it is today, based on this work.

TLSR: When does Trillium Therapeutics move forward and attempt to get a NASDAQ listing?

BB: I don't believe Trillium has said just yet on which exchange, or when. It wants to list in the U.S., and the company has certainly sent a signal to the market with its name change from Stem Cell Therapeutics to Trillium Therapeutics. At its last annual shareholder meeting, Trillium was granted permission from its shareholders to reverse split its stock, and I believe the company could seek a U.S. listing in the second half of 2014.

TLSR: What other companies do you wish to discuss?

BB: BELLUS Health Inc. (BLU:TSX; BLUSF:OTCPK) is another of our favorite biotechnology companies. It has a long history in the capital markets, previously as Neurochem Inc., where it conducted a Phase 3 study with an Alzheimer's program that has since failed. The company renamed itself BELLUS Health and has since focused very intelligently on other assets, with a new focus on orphan disease, a strategy where you target smaller patient populations but where you have a higher probability of success due to a more supportive regulatory and commercial pathway.

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BELLUS' lead program is Kiacta (NC-503; eprodisate disodium) for the treatment of AA amyloidosis. Kiacta previously was the subject of a Phase 2/3 clinical trial, in which the results were mixed. But there were positive efficacy signals, prompting the U.S. Food and Drug Administration (FDA) to ask the company to conduct a confirmatory Phase 3 trial. This study, with 230 patients, has been slightly redesigned—all to the favor of Kiacta—with refinement of endpoints and patient- or subject-selection criteria. We believe the company has a higher probability of success in its current Phase 3 study than it did in its original Phase 2/3.

TLSR: At the end of Q1/14, BELLUS reported a cash position of $14M on its balance sheet. Is that sufficient to carry the company forward?

BB: Yes it is. The Kiacta program has been capitalized by a U.S. fund called Auven

Therapeutics Management LLLP. It is a project-based financing group, and it has significant development and regulatory expertise. Auven and BELLUS formed a joint venture (JV), in which BELLUS contributed the Kiacta assets while Auven contributed more than $50M in the development of the current Phase 3 program and will share in the monetization of the proceeds if the drug is successful.

We also like BELLUS Health because in early May it announced that it had engaged Lazard as its financial advisor. Lazard is among the preeminent biotechnology merger and acquisition advisory firms in the United States, and is currently acting on behalf of the BELLUS-Auven joint venture to see whether it could be partnered or monetized before Kiacta's Phase 3 data. This is a very long clinical trial, and we don't expect data to be in-hand until 2016 or 2017. However, we believe Lazard may succeed in finding the right price in advance of the data and that could be very meaningful for BELLUS, which has a very small market cap of approximately $CA54M, and $CA14M in cash. We have a Phase 3 program with an enterprise value of $CA40M that has a fully funded Phase 3 program with a capable development partner and now a very capable banking firm to represent the asset to larger companies who may wish to commercialize Kiacta.

TLSR: AA amyloidosis is an orphan disease, and BELLUS says there are about 50,000 patients in the U.S., Europe and Japan. I saw a company presentation saying that peak revenues could be $US400–600M. What could this product be worth today if BELLUS and Auven divest Kiacta?

BB: We don't have formal models on BELLUS Health at the moment. However, most biotechnology products are valued conservatively at approximately two times peak sales at the time of regulatory approval. If we assume Kiacta is a $500M peak-sale product, it would infer an asset value of approximately $US1 billion ($US1B), post-FDA regulatory approval. Split equally between Auven Therapeutics and BELLUS Health, this could mean $US500M to each partner in the JV. I could discount that using a simple probability of successful-approval factor of 50%, and it's highly plausible that if the JV were monetized today, it might be worth several hundreds of millions of dollars in total, or from $US100–200M for BELLUS Health's share of the JV. That would obviously be a significant premium to where the company is trading today, at $US48M valuation.

TLSR: If Kiacta is partnered or sold to a pharma, this would be an immediate catalyst that would far precede any kind of data emanating from a Phase 3 trial, correct?

BB: Yes. Additionally, Lazard could assist the JV in seeking a commercial partner that may wish to share risk and pay a substantial upfront fee, while leaving additional milestones and future considerations on the table. That also would be highly accretive to BELLUS Health's current share price.

TLSR: Would you discuss any companies on the TSX Venture Exchange?

BB: Tribute Pharmaceuticals Canada is my favorite specialty pharmaceutical company right now, based on its valuation. CEO Rob Harris and CFO Scott Langille were both leaders in helping Biovail Corp. launch its Canadian, and then American, commercial infrastructure. They were responsible for Biovail's business development and commercial activity—via both licensing and acquisition—and growing Biovail into a multibillion-dollar company. Tribute Pharmaceuticals is an earlier-stage version of Biovail.

The Canadian specialty pharmaceutical sector has performed better than any other

"You either have to have a lot of expertise or be crazy

on the TSX in 2013. Multiples to both revenue and EBITDA have never been higher for this group. The reason we like Tribute is that it's trading at two to three times sales versus its Canadian peers, which are trading at four, five or more times annual sales. We believe this arbitrage will be closed soon.

Tribute recently listed its shares on the TSX Venture Exchange, and this will allow Canadian investors to buy its shares and assist in narrowing the valuation arbitrage. The company will also look to potentially list on an even higher-profile U.S. exchange in the future.

Many companies, such as Merus Labs and Concordia Healthcare, have done an amazing job at purchasing legacy pharmaceutical products at low multiples in a roll-up strategy that has served shareholders very well. However, in addition to purchasing legacy brands, Tribute is also a pharmaceutical company with a real sales and marketing infrastructure, with 25 sales reps in Canada. It's an ideal partner for American and European companies that get drugs approved internationally but don't yet have a commercial plan or infrastructure for the Canadian marketplace. Licensing the rights to drugs in Canada is a strategy that Biovail employed for many years. Paladin Labs also employed this model, and went from a startup to a $3B acquisition by Endo this year. Tribute is now employing this focused and proven strategy in a differentiated way from some of its peers.

TLSR: You were pointing to the low multiple of market cap to revenue with Tribute trading at two to three times sales. Can it grow revenues from here to get investors' attention?

BB: Tribute has more than half a dozen drugs now, and many of them are just being introduced into the Canadian marketplace. Many of these drugs could peak at $10M or more. We love the idea that Tribute Pharmaceuticals is undervalued in comparison to its peers, and yet has tremendous growth potential with the products it has licensed from international pharma companies for launch into the Canadian marketplace. And, as mentioned, Tribute is actively seeking to acquire legacy pharmaceutical assets, which would provide it with cash flow that can be further invested in its growth products.

TLSR: I'm noting that Tribute is now selling eight products in Canada, and some internationally, yet it has a low market valuation, at about $CA28M or $US30M. Is this story misunderstood by the Street?

BB: No. I believe it's just unknown, and I believe that will change now that it is on the TSX Venture and newly available to more Canadian investors, including those who have developed an a strong appetite for commercial-stage healthcare companies.

TLSR: Are there other companies you would like to discuss?

BB: Tekmira Pharmaceuticals Inc. (TKMR:NASDAQ; TKM:TSX) is a leader in RNA interference (RNAi) formulation and delivery technologies. The company combines elements of Alnylam Pharmaceuticals Inc. (ALNY:NASDAQ), which is the platform technology leader in RNA interference technology, with elements of Arrowhead Research Corp. (ARWR:NASDAQ), which is laser-focused on certain diseases indications and specific products.

Tekmira is carving out a niche as a leader in the RNAi approach to infectious disease. It has programs in hepatitis B, as well as in Ebola virus disease, which

used to be known as hemorrhagic fever, a severe and too often fatal disease in humans. There are some legacy programs in oncology, both partnered and being developed by Tekmira. We also understand that the company is exploring genetic orphan diseases.

TLSR: This company has a solid small-cap valuation of about $US300M. How is it positioned for all these difficult development programs you're talking about?

BB: Tekmira has raised approximately $90M in follow-on offerings over the past year, and it had more than $US130M in cash on its balance sheet on March 31. The company is cashed up, and the financial risk has therefore been dramatically diminished. It has cash to fuel research and development for many years. The enterprise value, at about $US170M, is trading at a significant discount to its peers, and the company has a very strong scientific team, as well as a very impressive clinical and regulatory team and experienced leadership. We believe all these factors combine to make Tekmira Pharmaceuticals one of the most undervalued and exciting biotechnology companies around.

TLSR: Tekmira's long list of indications looks very difficult because these are all systemic diseases. What does Tekmira have that's special? How does it get around oligonucleotide delivery problems?

BB: Delivery is a huge challenge for all RNAi companies. Tekmira's claim to fame is its lipid nanoparticle (LNP) formulation technology, which delivers systemic RNA/LNA particles to the liver and other organs.

Tekmira has been able to fine-tune both the size and nature of its LNPs to work in various situations. It has partnerships and cross-license agreements with other pharmaceutical companies, and through many successive generations of technology improvements, I anticipate Tekmira might expand its pipeline with products that target organs other than the liver.

TLSR: Brian, I thank you.

Brian Bloom is a cofounder of Bloom Burton & Co., and serves as the firm's president and head of institutional sales and capital market activities. By forging unique relationships with international healthcare-specialized investors, Bloom attracts capital for growing companies seeking to accelerate returns for investors. Before cofounding Bloom Burton, Bloom spent six years at Dundee Securities in the healthcare and biotechnology institutional sales and equity research groups. Earlier in his career, he spent two years in the equity research group at a New York-based merchant banking firm, SCO Group, and was an investment banking analyst at M&A advisory firm, Molecular Securities. Bloom is a member of the Life Sciences Advisory Board at the National Research Council of Canada and the Board of Directors at BIOTECanada. Bloom received an Honors Bachelor of Science degree in biochemistry from McMaster University and subsequently studied at the Mount Sinai Graduate School for Biological Sciences of New York University with a focus in molecular endocrinology and biophysics.

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