



## **BirchBioMed Issues Letter to Shareholders**

**VANCOUVER, BC (March 28, 2019) – BirchBioMed Inc.**, a clinical-stage biomedical company focused on the clinical evaluation, development and commercialization of anti-scarring drugs, autoimmune therapeutics and novel strategies for transplantation, has issued the following letter to shareholders. It may be found on the Company's website at [www.birchbiomed.com](http://www.birchbiomed.com).

### **To My Fellow Shareholders:**

The team at BirchBioMed has made excellent progress in developing our proprietary platform drug FS2 since our spinoff from the University of British Columbia in 2016. Indeed, we spent much of 2018 preparing for a number of significant milestones expected in 2019, some of which have already been achieved. As you know, the potential of FS2 to improve the lives of many people drives us day-to-day as we work toward the time when FS2 will be used in a host of indications, including scar reduction and prevention, and in autoimmune diseases such as diabetes and alopecia. We've worked tirelessly to capitalize our company so that we can advance late-stage clinical studies and secure product to supply both clinical studies and commercial avenues. Although there is still much to do, I am delighted to report that we are firmly on the right path.

### **Near-term Commercial Opportunity**

During 2018 we signed an agreement with Sensus Healthcare to produce a skincare product, formulated with FS2, that keloid patients will apply twice daily to hydrate and prevent the return of keloid scars following excision. The FS2 product will be distributed and branded under this partnership for use following the administration of Sensus' superficial radiation therapy (SRT). As our distributor, Sensus gives us early entry into the keloid market segment as an adjunct to treatment with SRT. Both companies share the mission to create improved products that provide an effective option for patients and physicians to treat keloids. The initial revenue provided by this launch will assist in supporting our efforts to advance FS2 in other indications. We are now just weeks away from formalizing the agreement and putting product into the offices of Sensus' dermatology and plastic surgery customers.

We remain committed to pursuing other partnership opportunities for the FS2 platform and have identified target partners who might offer alternative commercial channels. We are making progress with these discussions, including exploring private-label opportunities, and look forward to updating you on our progress. These discussions are focused on the use of FS2 in moisturizing creams distributed through dermatology offices. We are hopeful we will consummate an agreement during the first half of 2019.

### **Progressing with Clinical Studies of FS2 Technology Platform**

We continue to advance clinical development of our FS2 platform, which prevents the excess buildup of proteins that form scar tissue and promotes the breakdown of existing scars, all at the

molecular level without interfering with wound healing. We believe this is a revolutionary approach, as there are no products on the market that work to do this at the molecular level. Currently, there are numerous costly cosmetic treatments that demonstrate little, if any, efficacy in treating scars and instead simply moisturize the skin. Currently available medical alternatives focus on healing wounds, not preventing or ameliorating disfiguring scars. Our solution addresses an unmet global need that represents an annual market opportunity of approximately \$60 billion, according to a March 2018 report by Zion Market Research.

Data from our Phase 1 clinical trial demonstrate safe topical administration, and since then we have enrolled patients in a subsequent clinical trial to demonstrate efficacy in treating keloids and hypertrophic scars. This study is expected to be completed in July of this year. We also plan to enroll patients in a second clinical trial that will focus on preventing scars in trauma and burn patients undergoing skin grafts, beginning in May. These trials are as follows:

- A scar-reduction study to treat keloids and hypertrophic scars is a 125-patient, randomized, double-blind, dose-finding, placebo-controlled and comparative trial, with final assessment 120 days after initial treatment. Consequently, we expect to report results from this study in mid-2019. We are honored to have one of our Scientific Advisory Board members, Dr. Mark Nestor, conducting the study. Dr. Nestor is a world-renown expert in wound care, dermatology and immunology, a Voluntary Associate Professor in the Department of Dermatology and Cutaneous Surgery at the University of Miami Leonard Miller School of Medicine, and Director of the Center for Cosmetic Enhancement® and Director of the Center for Clinical and Cosmetic Research in Aventura, Florida.
- A trial focused on the prevention of scars in trauma and burn patients at Vancouver General Hospital is expected to enroll between 23 and 50 patients who will undergo daily treatments with FS2 for 90 days. Final assessment will take place 270 days after initial treatment. As this is a skin-grafting study, each patient can serve as his or her own control. We are pleased to have another Scientific Advisory Board member, Dr. Anthony Papp, as the principal investigator for this study. Dr. Papp, a world-renowned surgeon/clinician and leading authority on burn trauma and scarring, is the Medical Director for the British Columbia Professional Firefighters' Burn Unit at Vancouver General Hospital, where he leads the Provincial Burn Program with responsibilities in teaching and research, as well as patient care. In addition, he is a Clinical Professor of Plastic Surgery at the University of British Columbia and the plastic surgeon responsible for the Spinal Cord Injury Wound Clinic and Complex Wound Clinic.

## **The Year Ahead**

2019 got off to a busy start as Dr. Ryan Hartwell, our Chief Science Officer, and I presented at the 17<sup>th</sup> Annual South Beach Symposium in February. I participated in the Symposium Industry CEO Forum with a panel discussing our FS2 platform and partner relationships. I was pleased with the reception my talk received and the subsequent interest in BirchBioMed that it generated, as several commercial follow-up discussions with attendees are planned and/or are in progress. Dr. Hartwell's presentation focused on the current anti-fibrotic research and development landscape, including BirchBioMed's FS2 platform and its concomitant use with SRT and with immunomodulatory drugs. In addition, we hosted a collaborative advisory board during the conference, which included luminaries from both dermatology and industry. More recently, in March we attended the American Academy of Dermatology annual meeting in Washington, D.C., where we continued to network on behalf of the Company with potential partners.

In addition to the scar indication, we are encouraged by proof-of-principal results with FS2 in certain autoimmune diseases. Our investigators demonstrated in preclinical animal models that FS2 administered in conjunction with AI-001 cell therapy is able to reverse a number of autoimmune diseases, including type 1 diabetes, psoriasis and alopecia (disfiguring hair loss). We plan to request an Investigational New Drug meeting with the FDA by the end of the year, to pursue other fibrotic conditions and clinical studies in either type 1 diabetes or alopecia in 2020.

Pending anticipated progress both commercially and clinically, we are hopeful we will be able to become a publicly traded company by the end of 2019, or early in 2020.

### **Annual General Meeting of Shareholders**

Our independent auditors are completing their work on the Company's 2018 financial statements for our annual meeting of shareholders. We will be scheduling this meeting sometime in May, more details will follow.

### **Closing Thoughts**

BirchBioMed is at an inflection point with multiple significant milestones anticipated in 2019, including data from our clinical studies and the initial commercial launch of our first FS2 product. We look forward to advancing the development of our proprietary compound and to updating you on our progress. We firmly believe BirchBioMed has the ability to positively impact the lives of millions of patients. I would like to thank our employees for their outstanding work and commitment, our researchers for their excitement and dedication, and our investors for their continued support.

Sincerely,



Mark S. Miller  
Chairman & CEO

### **About BirchBioMed**

BirchBioMed Inc. is a biomedical company focused on the commercialization, clinical evaluation and development of proprietary anti-scarring drugs, autoimmune therapeutics/therapies and novel strategies for transplantation. As a University of British Columbia (UBC) spinoff, BirchBioMed holds the exclusive, worldwide pharmaceutical license for two medical therapeutic technologies from UBC, which the university considers to be significant medical breakthroughs in the treatment of scarring and certain autoimmune diseases.

### **Company Contact:**

Susan Elliott  
905-833-0826  
susan.elliott@birchbiomed.com  
[birchbiomed.com](http://birchbiomed.com)

### **Investors:**

LHA Investor Relations  
Kim Sutton Golodetz  
212-838-3777  
kgolodetz@lhai.com

# # #