

# Leading BioSciences

March 24, 2014

U.S. Securities and Exchange Commission  
Attn: Elizabeth M. Murphy, Secretary  
100 F Street NE  
Washington, DC 20549-1090

Re: File No. S7-11-13

Proposed Rule Amendments for Small and Additional Issues Exemptions under Section 3(b) of the Securities Act, Release Nos. 33-9497; 34-71120; 39-2493

Dear Chair White, Commissioners and Commission Staff:

As a growing biotech company that hopes to utilize the JOBS Act's Regulation A+ offering in the near future, Leading Biosciences is pleased to submit these comments for consideration.

We applaud the Commission staff for the effort involved and open process leading up to the release of the Proposed Rule Amendments (hereafter Reg A+ Proposal) because we believe it represents major progress toward accomplishing Congress' JOBS Act goal of expanding access to capital for innovation-producing, job-creating growth companies like Leading Biosciences.

## Summary

- Because the Reg A+ Proposal includes robust investor protections, federal preemption should be retained in the final release as a critical piece to making the Tier 2 proposal successful for growing companies like Leading Biosciences.
- The proposed Investment Limitation should be raised and exempt Accredited Investors.

## About Leading Biosciences

Leading Biosciences (LBS) is a growing biotech corporation established in 2005 with headquarters in San Diego, CA. The business model utilized is to in-license promising biotechnology

developed at Universities, invest in the technology in a sufficient amount to move the technology into human trials, and then move into commercialization with either internal company resources or resources from a Pharma partner.

To date, the model has been successful as the company has in-licensed 16 technologies from the University of California San Diego with the lead technology being a treatment for multi-organ failure as a result of various types of shock, including septic shock. The National Center for Health Statistics ranked “septicemia” (which may progress to septic shock) as the single most expensive reason for hospitalization in the United States in 2011. Four patents have been issued on the technology and there are an additional 25 filings made in the US, PCT and National stage.

LBS’ Clinical collaborators have treated 154 patients in the US and Taipei with excellent results. The clinicians in Taipei have treated 103 critically ill patients under consent, have completed a 46 patient Phase 1 safety trial, and anticipate starting a Phase 2 treatment trial in Q2 of 2014. LBS has completed a pre-IND meeting with the FDA and has received permission to skip a Phase 1 and move directly into a Phase 2 trial in the US once the IND is opened. A Phase 2, 200 patient, 20 site trial is anticipated to start in late 2014 in the US.

LBS has five full-time employees, offices in San Diego and New York, eleven outside personnel involved on its Boards and has a network of outside surgeons and clinical collaborators. To date, the company has raised over \$8 million in capital from Accredited and Institutional Investors and is currently opening a \$35 million Series B Institutional round.

LBS would have much preferred pursuing a Reg A+ offering and thus felt compelled to provide the Commission these comments to help inform the process toward swift finalization of a Final Rule. The \$35 million Series B will be sufficient to complete the Phase 2 study and qualify for a “Breakthrough Therapy” designation. The next step would be a Reg A+ offering which would provide enough capital to complete the FDA approval process and enter into commercialization. The therapy for multi-organ failure represents a market opportunity exceeding \$5 billion annually in the U.S. and we are excited about the opportunity to provide these life-saving treatments to patients while improving healthcare globally.

A. Because the Reg A+ Proposal includes robust investor protections, federal preemption should be retained in the final release as a critical piece to making the Tier 2 proposal successful for growing companies like Leading Biosciences.

A review of the Advance Comments that were filed ahead of the release of the Reg A+ Proposal shows strong support for the Commission’s warranted step to preempt state securities law in the Reg A+ Proposal. We believe the data reveals that retaining Tier 2 federal preemption is the key factor to ensure that Reg A utilization increases in a way that makes Reg A+ a significant game-changer for growth companies on the cusp of economically-measurable expansion. Coupled with the broad investor protections in the Reg A+ Proposal, plus the clear delegation of authority by Congress to act, the Commission should retain federal preemption in the final release.

For a growing biotech company like Leading Biosciences that is well beyond the proof of concept stage but is not yet ready to go public, Reg A+ could become the perfect stepping stone to a future IPO or IPO On-Ramp process if preemption stays part of a Final Rule. Without preemption the time, expense and potential uncertainty of merit-based review filing in multiple states could make Reg A+ extremely unattractive as a new capital-raising pathway. We believe other growing biotech companies would also be resistant to enter the process. Unfortunately, this means that new, well-paying jobs won't be created, new technologies across various industry sectors will sit dormant, and the public will miss out on new products that could change their lives or advance the common good.

In addition to the majority of the Advance Comments that reveal enthusiastic support for preemption not only in the capital markets professional community, but also from growing companies that will use Tier 2, other evidence demonstrates the solid foundation that supports the Commission in retaining Tier 2 preemption. To begin with, the congressionally mandated Government Accountability Office's July 2012 report to Congress on "Factors That May Affect Trends in Regulation A Offerings." The GAO report included input from various stakeholders, stating that "identifying and addressing individual state's securities registration requirements can be both costly and time-consuming for small businesses..."<sup>1</sup>

In addition to the GAO's research showing stakeholders support preemption, the Recommendations of the SEC's own Forum on Small Business Capital Formation in both 2011 and 2012 strongly supported preemption.<sup>2</sup> However, we contend that the most persuasive data on why preemption is necessary to make Reg A+ successful comes from a more recent SEC study.

In July 2013, the SEC Division of Economic and Risk Analysis released an updated report entitled, "Capital Raising in the U.S.: An Analysis of Unregistered Offerings Using the Regulation D Exemption, 2009-2012."<sup>3</sup> In the section where the report compares the dominating prevalence of Rule 506 utilization in contrast to Rule 505 and Rule 504 utilization, the report highlights a remarkable revelation that powerfully makes the case for preemption in Reg A+ Proposal,

Table 2 shows that Rule 506 is the dominant offering method even among those offerings eligible for Rules 504 and 505. Almost 50% of all Rule 506 offerings by non - funds since 2009 were for \$1 million or less and therefore may have qualified for the Rule 504 exemption based on offering size, but issuers elected to claim the Rule 506 exemption. An additional 20% of offerings were for between \$1 million and \$5 million and therefore could have claimed a Rule 505 exemption based on offering size. *This evidence suggests that the Blue Sky law preemption feature unique to Rule 506 offerings has greater value to issuers than the unique features of Rule 504 or Rule 505 offerings.*<sup>4</sup> (Emphasis added)

Thus, when similarly situated offering exemptions were presented to companies seeking to raise capital, overwhelmingly the companies chose the option which includes preemption. Consequently, if the Reg A+ final rule includes the preemption option Congress has allowed, it is more than reasonable to conclude that the attractiveness of Reg A+ will be dramatically increased.

We know that some strong comments are opposed to preemption and recognize the courage it will take for Commissioners to approve the preemption proposal as written, but we strongly

encourage Commissioners to retain Tier 2 preemption as set out in the Reg A+ Proposal because it is the right policy solution. Additionally, preemption is the most practical solution to increase access to capital for Tier 2 innovation companies that are ready to scale like Leading Biosciences, while also protecting investors.

B. The proposed Investment Limitation should be raised and exempt Accredited Investors.

The Reg A+ Proposal significantly upgrades investor protections and the amount of information a potential investor will be able to review before making an investment decision. The Commission's effort to increase investor protections in such a robust way provides an appropriate balance to the increased Tier 2 cap. Despite the good work accomplished by the Commission with the new investor protections generally, we suggest some ways to make the investor limitations a bit more flexible to further facilitate access to capital without substantially reducing investor protections.

First, we assert that the 10% annual income/net worth limit should, at a minimum, be raised substantially if not eliminated. As mentioned in the explanatory statement in the Reg A+ Proposal release (p. 52), the limit is similar to the "loss limitation" in the recently proposed crowdfunding regulations. However, we believe that more mature Tier 2 growth companies should not be limited in the same way that crowdfunding startups would be limited.

Growth companies like Leading Biosciences have already proven their viability beyond proof of concept, have already successfully raised capital and are positively progressing through the commercialization process. Growth companies provide investors a track record that is far more extensive and able to be scrutinized as compared to crowdfunding startups that will likely have thin or no track records because of their nascent development stages they are struggling to traverse. Although the 10% limit for crowdfunding appears reasonable because of the greater risk an investor undertakes, that same 10% limit does not seem properly calibrated for more mature growth companies needing Tier 2 to boost them to the next plateau of growth, technology development and job creation. Thus, we contend that the Commission should consider at least doubling the limit if not eliminating it altogether.

Second, we believe Accredited Investors (AIs) should be totally exempted from the Investment Limitation because of their ability to analyze, assess, and weigh the risk and reward of a Tier 2 investment. Accredited Investors generally have the sophistication, experience, and collaborative networks to engage in Tier 2 investments in various amounts as they and their AI colleagues best determine. Thus, we contend that the Commission should completely exempt AIs from the Investment Limitation.

Finally, we believe that companies utilizing Tier 2 be allowed to rely on the investor's representation of compliance with any Investment Limitation as to not increase undue administrative obligations and liability on a growth company.

## Conclusion

We again want commend the effort by the Commission staff to develop the well-balanced Reg A+ Proposal. We are also grateful that Chair White has publicly stated that JOBS Act implementation continues to be a top priority for the Commission. We respectfully encourage the Chair, Commissioners and Commission staff to swiftly finalize a Rule Proposal that embodies the balanced approach presented and remains mindful of the resource limitations growing companies face leaving such companies to stay focused on disruptive innovation and job creation.

Leading Biosciences is a perfect example of the promise of the JOBS Act and the bipartisan ideals expressed by both the President and Congress in enacting the law. We are confident and ready to make those bipartisan promises a reality and move our country and globe to having access to our therapies that can wipe out the tragedy of septic shock.

We would be happy to further assist you in any way beyond these comments or to answer any questions you might have.

Sincerely,



John Rodenrys  
Executive Director R&D  
Leading Biosciences, Inc.

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<sup>1</sup> GAO-12-839, Highlights p.2, <http://gao.gov/assets/600/592113.pdf>

<sup>2</sup> SEC Government Business Forum on Small Business Capital Formation Final Report 2012, pp. 25-26 <http://www.sec.gov/info/smallbus/gbfor31.pdf> and Final Report 2011, pp. 29-30 <http://www.sec.gov/info/smallbus/gbfor30.pdf> The 2013 Forum report is not yet available.

<sup>3</sup> <http://www.sec.gov/divisions/riskfin/whitepapers/dera-unregistered-offerings-reg-d.pdf>

<sup>4</sup> Id at p. 7.