August 9, 2012

AN OPEN LETTER TO THE SECURITIES AND EXCHANGE COMMISSION FROM EXECUTIVES OF U.S. SMALL BIOTECHNOLOGY & MEDICAL DEVICE COMPANIES REGARDING JOBS REGULATIONS UNDER THE JOBS ACT: TITLE II, ACCESS TO CAPITAL FOR JOB CREATORS

Dear Honorable Commissioners:

The undersigned leaders of small U.S. biotechnology and medical device firms are very optimistic about the Jumpstart Our Business Startups Act (the "JOBS Act") signed into law on Apr. 5, 2012 by President Obama.

We are especially enthusiastic about Title II of the Act which will soon permit us to use publicity, press releases, advertisements, etc. to identify qualified investors for our businesses. Many investors in medical technology start-ups seek to accelerate the development of novel treatments to diseases in which they have a strong personal interest. We need effective ways to make introductions to these potential investors beyond personal contacts and broker/dealers. However regulations that require us to make intrusive or burdensome requests of investor prospects as to their net worth, income etc. will certainly turn these investors away.

Several of us were fortunate to have held a constructive meeting with SEC staff on July 31, 2012 to discuss the regulations that will allow general solicitation or general advertising provided that the issuer takes "reasonable steps to verify that purchasers of the securities are accredited investors, using such methods as determined by the Commission." We urged that the Commission not alter or expand Rule 506 in a way that increases the burden on, or risk to, those using the Rule 506 exemption. Clearly, additional burdens on Rule 506 issuers who engage in general solicitation or general advertising would make it more difficult for small firms to raise capital. It would increase their cost of raising capital, make it less likely they will find much needed investments, and make it less likely that investors will invest in small firms. This runs countercurrent to the general purposes of the Act.

Most of us have for years verified the accreditation status of our investors with a simple questionnaire that is completed and signed by the investor. We see no reason why that practice needs to change with the JOBS Act. The SEC staff, however, indicated their belief that Congress intended for the SEC rules to go beyond self certification by investors identified in a general solicitation. They voiced concern, in particular, with "point and click" impulse investments over the internet by naïve investors who lack the ability and experience to assess the risks of their investments. They asked us for specific ideas on procedures that would go beyond current practice but not overly burdening investors and entrepreneurs. While we respectfully disagree with the SEC staff on the need to go beyond existing self certification practice we nevertheless offer the Commission the following suggestions.

Investors that follow a general solicitation could self certify their accredited investor status without corroborating evidence in any <u>one</u> of the following three circumstances:

Small Biotechnology Business Coalition • 9710 Traville Gateway Drive, #325 • Rockville, MD 20850
(301) 917-6538 • www.smallbiotech.org

1. ***Investments of more than $25,000.*** Investors capable of investing this amount are more likely to have a net worth or income to meet the accredited investor status and will not invest on a mere impulse.

OR

2. ***The investor has personally met the issuer.*** This better enables the issuer and investor to assess one another merely than through an electronic exchange.

OR

3. ***At least 30 days pass between the public solicitation and the investment.*** This waiting or "cooling off" period will help discourage impulse investments and will permit the issuer and investor to assess one another.

In situations where none of the above three criteria can be met we suggest that the investor be required to furnish a letter from an attorney, CPA, or registered broker-dealer, who knows the investor, asserting that, to the best of his/her knowledge, the investor meets the accreditation standards. This additional corroboration by the issuer will provide a significantly higher level of confidence of investor accreditation, and fully comply with the intent of the "reasonable steps" requirement. However, **in no circumstances should the investor be required to furnish the issuer with net worth statements, tax returns or the like.**

We thank the Commission for the opportunity to provide input.

Sincerely,

Darryl Sampey
President and CEO
BioFactura, Inc.
9430 Key West Ave., Suite 125
Rockville, MD 20850

Kenneth C. Carter, CEO
NexImmune
22 Firstfield Road
Gaithersburg, MD 20878

Casimir Eitner, President
Biotech Venture Management
5149 Nebraska Ave., NW
Washington, DC 20008

Dr. Arthur DeCarlo
President & Science Director
Agenta Biotechnologies, Inc.
Innovation Depot
1500 1st Ave. N. Unit 31
Birmingham, AL 35203

Ralph Kauten, CEO
Quintessence Biosciences, Inc.
505 South Rosa Road
Madison, WI 53719

Martin Woodle, Ph.D.
Chief Executive and Scientific Officer
AparnaBio
12111 Parklawn Drive
Rockville, MD 20852

Jonathan Cohen
CEO & President
20/20 GeneSystems, Inc.
9430 Key West Ave. Suite 100
Rockville, MD 20850

Bruce D Weintraub, MD
President & CEO
Trophogen, Inc
6 Taft Court, Suite 150
Rockville , MD 20850

Jerry Stringham, President
Blue Torch Medical Technologies, Inc.
9700 Great Seneca Highway
Rockville, MD 20850

Frederick R. Blattner CEO
Scarab Genomics LLC
202 Ann St.
Madison WI 537113

Bettie V. Sogor
President/CEO
BioBiz Navigator, LLC
P.O. Box 5668
Cleveland, OH 44101

Jonathan Kaufman, CEO
Lipella Pharmaceuticals Inc.
400 N. Lexington Ave. Suite LL103
Pittsburgh, PA 15217

Phyllis Siegel, CEO
Biomedical Development Corp.
500 Sandau Road
Suite 200
San Antonio, Texas 78216

Deven McGlenn, CEO
NeoClone, LLC
1202 Ann St.
Madison, WI 53713

Michael P. Vitek, Ph.D.
Chief Executive Officer
Cognosci, Inc.
Research Triangle Park, NC 27519-5606

Gary Fujii, Ph.D.
President and CEO
Molecular Express, Inc.
2011 East University Drive
Rancho Dominguez, CA 90220

Richard Tamaki
Secretary and COO
Molecular GPS Technologies
2011 University Drive
Rancho Dominguez, CA 90220

Aprile L. Pilon, Ph.D.
President & CEO,
Clarassance, Inc.
9700 Great Seneca Highway
Rockville, MD 20850

Nancy Kendrick, Ph.D.
President
Kendrick Labs Inc
1202 Ann St
Madison, WI 53713