SIGNAL GENETICS, INC.
Form FWP
February 02, 2015

Issuer Free Writing Prospectus

Filed Pursuant to Rule 433

Registration No. 333-201533

February 2, 2015

Signal Genetics, Inc.

Free Writing Prospectus

We have filed a registration statement (including a preliminary prospectus) with the Securities and Exchange Commission (the “SEC”) for the offering to which this communication relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in that registration statement and other documents we have filed with the SEC for more complete information about us and this offering. You may get these documents for free by visiting EDGAR on the SEC website at www.sec.gov. Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you request it by contacting Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 18th Floor, New York, New York 10019, telephone: 212-813-1010, e-mail: prospectus@aegiscap.com.

The following press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of, these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state or jurisdiction.

Forward-Looking Statements

All statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for us and its products and services, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements.

Any statements that are not historical fact (including, but not limited to, statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements.

By their nature, forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights and other risks discussed in our quarterly report on Form 10-Q and other reports filed with the SEC, which are available for review at http://www.sec.gov/.

Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect our business. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation, except as required by law.

On February 2, 2015, we issued the following press release.

Signal Genetics Receives Conditional Approval of Investigational Device Exemption for MyPRS®

Carlsbad, CA, February 2, 2015 – Signal Genetics, Inc. (NASDAQ: SGNL) (Signal), a commercial stage, molecular diagnostic company focused on providing innovative diagnostic services that help physicians make better-informed decisions concerning the care of their patients suffering from cancer, today announced the U.S. Federal Drug Administration (FDA) conditionally approved its proprietary prognostic genetic test, MyPRS (Myeloma Prognostic Risk Signature®), for use as entry criteria for an upcoming clinical trial to treat high-risk multiple myeloma (MM) patients sponsored by the University of Arkansas for Medical Sciences (UAMS).

The FDA required and subsequently conditionally approved an Investigational Drug Exemption (IDE) for Signal's prognostic test in conjunction with an investigational new drug (IND) filed by UAMS for its "2012-02 Total Therapy 5B: A Phase II Trial for High-risk Myeloma Evaluating Accelerating and Sustaining Complete Remission (AS-CR) By Applying Non-Host-Exhausting and Timely Dose-Reduced MEL-80-CFZ-TD-PACE Transplant(s) with Interspersed MEL-20-CFZ-TD-PACE with CFZ-RD and CFZ-D Maintenance" designed to improve clinical outcomes of newly diagnosed MM patients with gene expression profiling (GEP) defined high-risk disease. The Phase II trial will assess safety and efficacy for the investigational treatment regimen, using MyPRS to qualify which patients are considered to have GEP defined high risk MM. The investigation is limited to a single testing site in the United States and 45 subjects enrolled (approximately 60 subjects screened and 14 subjects enrolled per year). The conditional approval requires UAMS to provide the FDA with further information over the next 45 days; however, UAMS is allowed to begin enrollment of the trial based upon MyPRS immediately after UAMS has obtained institutional review board (IRB) approval and submitted certification of IRB approval to FDA.

Samuel D. Riccitelli, Signal's President and Chief Executive Officer, commented, "This is a significant milestone for Signal Genetics, as it brings us a step closer to our goal of gaining 'Companion Diagnostic' status for MyPRS, our novel prognostic test. In addition, we believe this is further validation of our test and its ability to aid in the treatment of multiple myeloma patients, especially during this time in which regulation and scrutiny regarding laboratory developed tests have continued to increase. We are excited to be expanding our work with UAMS, our longstanding partner, and look forward to advancing to the next stages of diagnostic development and commercialization as we work toward improving the care of patients suffering from this severe form of cancer."

Dr. Gareth Morgan, Professor of Medicine and Director of the Myeloma Institute at UAMS, commented, "We are excited to begin this Phase II trial to treat high risk multiple myeloma patients by applying more frequent, but lower doses of chemotherapy. The use of MyPRS to aid in the selection of high-risk MM patients is critical to this trial. UAMS and Signal Genetics have reached a major accomplishment and believe that with the recent IND filing and receipt of a conditionally approved IDE for MyPRS, we have demonstrated to the FDA the potential benefits of our work for the MM patient population. We also believe the new clinical trial will provide further evidence for the need of physicians to make better-informed treatment decisions in order to improve patient survival rate and quality of life."

About Signal Genetics, Inc.

Signal Genetics, Inc., headquartered in Carlsbad, California, is a commercial stage, molecular diagnostic company focused on providing innovative diagnostic services that help physicians make better-informed decisions concerning the care of their patients suffering from cancer. The Company's mission is to develop, validate and deliver innovative diagnostic services that enable better patient-care decisions. Signal was founded in January 2010 and became the exclusive licensee in its licensed field to the renowned research on multiple myeloma performed at the University of Arkansas for Medical Sciences, in April 2010.

About University of Arkansas for Medical Sciences

UAMS is Arkansas' only comprehensive academic health center, with colleges of Medicine, Nursing, Pharmacy, Health Professions and Public Health; a graduate school; a hospital; a statewide network of regional centers; and seven institutes: the Winthrop P. Rockefeller Cancer Institute, the Jackson T. Stephens Spine & Neurosciences Institute, the Myeloma Institute for Research and Therapy, the Harvey & Bernice Jones Eye Institute, the Psychiatric Research Institute, the Donald W. Reynolds Institute on Aging and the Translational Research Institute. It is the only adult Level 1 trauma center in the state. UAMS has more than 2,865 students and 785 medical residents. It is the state's largest public employer with more than 10,000 employees, including about 1,000 physicians and other professionals who provide care to patients at UAMS, Arkansas Children's Hospital, the VA Medical Center and UAMS regional centers throughout the state.

INVESTOR CONTACT:

The Ruth Group

David Burke

Tel: 646-536-7009

dburke@theruthgroup.com