

SIGNAL GENETICS, INC.
Form FWP
February 02, 2015
Issuer Free Writing Prospectus

Filed Pursuant to Rule 433

Registration No. 333-201533

February 2, 2015

1 CONFIDENTIAL 1/31/2015 Investor Presentation © 2015 Signal Genetics , Inc. | All Rights Reserved

2 Forward Looking Statements All statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for Signal Genetics, Inc. (the “Company”) 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 the Company’s quarterly report on Form 10 - Q and other reports filed with the Securities and Exchange Commission (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 the Company's 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.

3 Free Writing Prospectus Statement This presentation highlights basic information about us and the offering. Because it is a summary, it does not contain all of the information that you should consider before investing. This offering may only be made by means of a prospectus. We have filed a registration statement on Form S - 1 (including a preliminary prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about the Company and the offering . You may get these documents for free by visiting EDGAR on the SEC web site at <http://www.sec.gov/>. The preliminary prospectus, dated January 29, 2015, is available on the SEC web site at <http://www.sec.gov/>. Alternatively, the Company or any underwriter participating in the offering will arrange to send you the prospectus if you contact Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 18th Floor, New York, New York 10019, telephone: 212 - 813 - 1010, e - mail: prospectus@aegiscap.com.

4 Offering Summary Over - Allotment Exchange / Ticker Use of Proceeds Sole Book - Runner 15% (100% Primary)
Nasdaq Capital Market / SGNL Expand commercialization efforts, fund continued development of new products &
services, working capital & general corporate purposes Aegis Capital Corp. Issuer Signal Genetics, Inc. Offering Size
Approx. \$7,500,000 of Common Stock (100% Primary)

5 Signal Genetics at a Glance Molecular diagnostic company focused on Multiple Myeloma (MM) Headquartered in Carlsbad, CA; CLIA - certified lab operations in Little Rock, AR Marketing a proprietary prognostic genetic test for MM - MyPRS ® Exclusive licensee to the intellectual property from research at the University of Arkansas for Medical Sciences (UAMS) – a leading center for treatment of MM Strong revenue base and early adoption by leading U.S. cancer centers \$4.3M of revenue for the full year 2014* Medicare reimbursement approval (Local Coverage Determination: Novitas – Jurisdiction H MAC) Approved coverage policy & in - network with Arkansas Blue Cross & Blue Shield Significant growth opportunity to drive profitability Large untapped market opportunity for expanding use of MyPRS ® in MM Potential for expansion of clinical indications for MyPRS ® into pre - cursor conditions to MM Partner with leading pharmaceutical companies for clinical trial service revenue and potential companion diagnostics – two collaborations secured to date Leverage proprietary position for new revenue streams from additional esoteric diagnostic services * Unaudited; mid - point of estimated range of \$4.1M to \$4.5M

6 Recent Accomplishments Since IPO in June 2014 Achieved 50% year - over - year volume growth in sales of non - UAMS MyPRS ® Received NY State DOH approval for MyPRS ® effective July 2014; test is now available in all 50 states Extended exclusive laboratory services agreements with UAMS through Sept 2017 Appointed experienced industry veterans to key management roles Increased selling organization from one to four FTE's Enhanced Company efficiencies Began transition to in - house billing and cash collections function using "software as service" model Completed move - in and transfer of functions to our new corporate HQ in Carlsbad, CA

7 Our Mission Develop, validate and deliver innovative diagnostic services that enable better patient - care decisions

8 What is Multiple Myeloma? Multiple Myeloma (MM) is a cancer of the patient's plasma cells Plasma cells (PC) are found in the bone marrow PC normally make antibodies that help fight infections Symptoms include fatigue, hypercalcemia, renal failure, bone damage and fractures S econd most prevalent blood cancer 83,360 patients in the U.S. living with MM 24,050 new diagnoses in 2014 in U.S. Tumors are molecularly highly heterogeneous making the disease difficult to manage and treat C onsidered incurable – 5 - year survival from diagnosis is 45% Deadliest blood cancer, responsible for 2% of all annual cancer deaths in the U.S. More people die from MM than from melanoma; the deadliest form of skin cancer 2014 NCI Statistics: [http:// seer.cancer.gov/statfacts/html/mulmy.html](http://seer.cancer.gov/statfacts/html/mulmy.html) 2003 - 2009 NCI Statistics: <http://seer.cancer.gov/faststats>

9 MM Pre - cursor Condition - AMG Figure recreated from Dispenzieri, Blood. 2014; 123(1) pg. 4 MM is preceded by a more common, clinically asymptomatic precursor phase Asymptomatic monoclonal gammopathy (AMG) Definition based upon degree of bone marrow infiltration by malignant plasma cells Patients with AMG lack MM related end - organ/tissue injury Classified as monoclonal gammopathy of unknown significance (MGUS) or asymptomatic MM (AMM) There are more than 3 million people in the U.S. >50 yrs. of age with MGUS Current techniques do not enable accurate identification of AMG patients that will convert to full - blown MM Risk of progression ranges from 1% to 10% per year Unmet clinical need for better models to predict progression Kyle et al, NEJM. 2006; 354(13) pg. 1362 - 1369 Dhodapkar et al, Blood. 2014; 123(1) pg. 78 - 85

10 MM – The Clinical Dilemma Highly heterogeneous & deadly cancer ; prediction of a particular patient’s outcome is difficult for physicians Current treatment modalities vary from “watchful waiting” – to multi - drug regimens, stem - cell transplants and experimental protocols The selection of the best treatment is highly dependent on the risk assessment of each patient’s particular form of MM The classic staging tests include clinical factors, cell morphology, chemical markers, imaging studies and genetic abnormalities Experts agree that current prognostic methodologies lack ability to adequately predict the level of risk associated with each patient’s MM – low - risk patients receive excessive treatment and high - risk patients receive too little treatment Selection of the best course of therapy is challenging given status of conventional prognostic tests Fonseca et al, Sem. In Oncology. 2013; 40(5) pg.554 - 566

Proprietary Assay for Prognosis of Multiple Myeloma Patients 11 MyPRS ®

12 MyPRS[®] Highlights Accurately stratifies patients into more high and low - risk categories and molecular disease subtypes Can spare a low - risk patient from unnecessary , potentially toxic treatment and helps doctors guide high - risk patients toward optimal therapy or clinical trials Precipitates a conversation with patients regarding prognosis Based upon 30 years of patient management and outcome experience from greater than 10,000 patients at University of Arkansas for Medical Sciences (UAMS) – we believe to be the largest body of evidence in the field Analytical validation & clinical utility demonstrated in over 4,500 patients documented in peer - reviewed publications from 17 unique patient data sets from 4 countries Protected by 12 issued patents and 21 pending patent applications MyPRS[®] enables a more personalized risk - adapted therapeutic strategy for MM patients

13 MyPRS ® Enables Precision Medicine for MM Patients Risk Classifier : measures the expression levels of 70 important genes which stratify high - risk vs. low - risk patients Outcome predictor : predicts outcome in newly diagnosed patients and is a significant prognostic factor in predicting post - relapse survival Subgrouping for therapy selection : MM subtyping via 700 gene signature to further inform treatment selection Virtual Karyotype : identifies common cytogenetic abnormalities by examining the expression of 816 genes All of the above drive a fit with the current healthcare environment: • Eliminate unnecessary therapy • Reduce costs • Improve outcomes Probability of 5 - year event free survival: 77% Probability of 5 - year overall survival: 83% Probability of 3 - year overall survival: 62% LOW RISK HIGH RISK Probability of 5 - year event free survival: 34% Probability of 5 - year overall survival: 38% Probability of 3 - year overall survival: 17% Newly Dx Patient: Post Relapse Patient: Shaughnessy et al, Blood. 2007; 109(6) pg. 2276 - 2284 Zhan et al, Blood. 2006; (108(6) pg. 2020 - 2028 Zhou et al, Blood. 2012; 119(21) pg. e148 - e150 Based on data accumulated at the University of Arkansas for Medical Sciences

14 MyPRS® Technology Affymetrix GeneChip® System Recognized international standard FDA cleared & CE marked for in vitro diagnostic use Validated across thousands of publications Work Flow Customer collects bone marrow aspirate and sends via FedEx® to our Little Rock, AR CLIA - certified facility Sample processed and gene expression data run through proprietary algorithms Results returned in one week (turnaround time equal to or better than most other standard tests) HG U133 Plus 2.0 GeneChip® Risk Gene Expression Profile GeneChip® 3000Dx v.2®

15 Market for MyPRS ® Relative S ize : 2014 target market to 2014 prevalence of AMG in the U.S. Estimate the total MM testing market at 36,000 patients per year Current MM clinical market share estimated at <3% Estimate addition of AMG indication will expand MyPRS ® market to >135,000 patients per year Kyle et al, NEJM. 2006; 354(13) pg. 1362 - 1369 NCI 2014 SEER statistics Company estimates 24,050 12,025 101,500 MyPRS® 2014 Market Potential MM Annual New Cases MM Annual Relapse Cases (co. est.) AMG Annual Cases (co. est.)

16 Sales & Marketing Target market is leading academic centers where most MM patients receive their care Magnet for MM patients due to difficulty in managing the disease 117 academic medical centers in the US 330 affiliated hospitals Target call - point within the cancer centers are MM specialists – hematologists/oncologists Addressable with small, elite sales team Currently employ 4 sales FTE's Believe we can achieve penetration with 7 – 10 FTE's Current Sales Territories [https://www.uhc.edu/about/our - members](https://www.uhc.edu/about/our-members)

17 Pharma / Biotech Partnering Opportunity Heavy activity in MM drug development 283 new drugs in early development Wide spectrum of pharma / biotech companies have programs in MM Our value proposition: Ability to identify high - risk patients likely refractory to current standard of care Subgrouping to route patients to specific drugs / classes of therapy Rich body of genetic data to support partner's approach to FDA with novel therapies Hired executive with extensive pharmaceutical company partnering experience to lead pharma partnering (former Genzyme Genetics) Demonstrated capabilities for addressing FDA requirements to develop companion diagnostics High - risk MM trial at UAMS MyPRS[®] used for patient entry criteria into the trial Successfully navigated the FDA IDE process International Myeloma Foundation <http://myeloma.org/ResearchMatrix.action?tabId=4&menuId=206&queryPageId=14> Path to companion Dx Clinical trial service revenue Ameliorates reimbursement risk

18 Portable Growth Strategy into “Near Neighbor” Heme Markets Multiple Myeloma AML CLL C all points
Reimbursement Pharma trials Genetically - targeted therapy Over - reliance on old technologies Chronic / repeat
testing Abbreviations Key : Heme = hematology, KOL = key opinion leaders, HEOR = health economic outcome
research, AML = acute myeloid leukemia, CLL = chronic lymphocytic leukemia

19 “Near Neighbor” Heme Market Opportunities NCI 2014 SEER statistics Company estimates 21,000 10,500 AML: 31,500 Newly Dx Relapse 16,000 5,333 CLL: 21,333 Newly Dx Relapse (poor prognosis) 24,050 12,025 MM: 36,075 Newly Dx Relapse MM + near neighbor heme targets yield total available market of 87,000 patients / year in U.S. Exceeds some major solid tumor markets including melanoma, bladder, kidney, etc. Survival / outcomes generally poor AML 3 year survival ~ 25% Essentially all CLL patients relapse after treatment, with ~33% poor prognosis Niche markets similar to MM with call points clustered in academic centers Major clinical trial activity highlights pharma interest and cross - market synergies Imbruvica (PCYC) currently approved to treat CLL now being tested in MM

20 MyPRS® Sales Trends Volume Trend Revenue Trend 0 500 1000 1500 2000 2500 3000 3500 4000 4500 2011
 2012 2013 2014 MyPRS® Test Volume UAMS Clinical UAMS Research Other Hospitals Pharma \$- \$500 \$1,000
 \$1,500 \$2,000 \$2,500 \$3,000 \$3,500 \$4,000 \$4,500 \$5,000 2011 2012 2013 2014 MyPRS® Revenue (\$000) UAMS
 Clinical UAMS Research Other Hospitals Pharma \$- \$100 \$200 \$300 \$400 \$500 \$600 \$700 2011 2012 2013 2014
 MyPRS® Revenue (\$000) Other Hospitals 0 100 200 300 400 500 600 2011 2012 2013 2014 MyPRS® Test Volume
 Other Hospitals 50% Growth Other Hospital 2014 revenue is net of a \$0.2M of negative change in estimate UAMS
 Clinical 2014 revenue is net of a \$0.2M of negative change in estimate

21 Reimbursement - MyPRS® Medicare LCD and AR - BCBS in - network status Developing clinical utility dossier with external collaborators and consultants Validate economic impact of MyPRS® Eliminate unnecessary treatment in low - risk MM Targeted, aggressive treatment for high - risk MM Improvement over conventional staging methods Hired experienced Vice President of Managed Care to lead initiative to pursue third - party payor contracts Leverage external billing partner software platform for billing & collections Continue expanding market footprint Broaden the base of healthcare insurance companies that approve reimbursement for MyPRS® Payor data as of September 30, 2014 41% 9% 39% 11% MyPRS® Payor Mix Revenue excluding UAMS Research Medicare Contracted Non-Contracted Direct Bill

22 Comprehensive Growth Strategy Further penetrate the U.S. market by increasing the geographic coverage of our sales force Currently 4 Sales FTE Expand to 7 - 10 FTEs, focus on Academic Centers Expand the diagnostic indications for MyPRS ® to include AMG One peer - reviewed publication in support already published – Blood; January 2014 Plan to sponsor additional clinical research to further validate clinical utility Pursue additional collaborations with Pharma companies that focus on MM therapy development Two collaborations secured to date (one completed in 2013) 283 new therapies in pre - clinical and Phase I development for MM (Source: IMF) Enhance our test offering with the addition of genomic tests important to physicians who care for MM patients Targeted gene sequencing and RNASeq for therapy selection Additional molecular and clinical tests for MM and AMG Port skill sets and experience into “near neighbor” heme markets The skills and market attributes that drive our success in MM can be leveraged for success in adjacent hematology markets Continued leverage of our UAMS relationship International Myeloma Foundation
<http://myeloma.org/ResearchMatrix.action?tabId=4&menuId=206&queryPageId=14>

23 Milestones for 2015 Continued growth in non - UAMS sales volume for MyPRS ® Development agreements with leading academic centers to further AMG indication and other new products/services Establish strategic partnerships with pharma companies Launch of new products & services – targeted Next Gen Sequencing Contracts with health insurance providers: get in - network for more covered patient lives

24 Our Team Samuel D. Riccitelli – President & CEO, Director Former EVP & COO for Genoptix, Inc. [NASDAQ: GXDX] Senior management positions with Becton Dickinson & Co. and Puritan - Bennett Corp. M.S. Eng. The University of Texas Tamara A. Seymour – Chief Financial Officer Former CFO HemaQuest Pharmaceuticals, Inc. and Favril, Inc. [NASDAQ: FVRL; now OTC: MMRF] MBA Georgia State University Michael C. Cerio – SVP Commercial Strategy & Business Development Former President & CEO Oncolome Diagnostics, Inc., Senior business development roles with Genzyme Corp. MBA Columbia University Ryan van Laar, Ph.D. – VP Research & Operations Former Agendia , Peter MacCallum Cancer Center, Regeneron Pharmaceuticals ,Inc., ChipDX, LLC Ph.D. Bioinformatics , University of Melbourne Sudipto Sur, Ph.D. – Chief Information Officer Former CEO Ansur Corp & Miralex Systems, Inc., Senior development roles at Sequenom, Inc. & Genoptix, Inc. Ph.D. Control Systems & Robotics, California Institute of Technology Bennett S. LeBow Founder, Chairman & Principal Investor MM survivor since 2003 – treated at UAMS Longtime supporter of MM research through numerous grants to UAMS, Harvard and others Robin L. Smith, M.D. CEO & Chairman, Neostem, Inc. [NASDAQ: NBS] Board of Trustees, NYU Langone Medical Center Chairman The Stem for Life Foundation Yale Medical School Douglas A. Schuling Former EVP & CFO for Genoptix, Inc. [NASDAQ: GXDX] Former CFO & COO for Point - of - Care Systems Former Hospital Group Controller, Nellcor Puritan Bennett Drake University David A. Gonyer, R.Ph. President & CEO and co - Founder, Evoke Pharma, Inc.[NASDAQ: EVOK] Former VP Strategic & Product Development, Medgenex, Inc. Former VP Sales & Marketing, Xcel Pharmaceuticals, Inc. Ferris State University School of Pharmacy Board Members

25 Investment Summary Growing business from novel prognostic MM assay based upon one of the largest patient outcomes datasets in the world today - MyPRS ® Substantial proprietary estate protects exclusive access to MyPRS ® Exclusive licensing agreement with UAMS for MM based discoveries - pursuing additional patent protected products and out - licensing opportunities Medicare coverage : LCD in place with comprehensive strategy to expand our reimbursement footprint Opportunity to expand the market for MyPRS ® into precursor conditions to MM – one peer - reviewed study completed for AMG Potential to leverage proprietary position for new revenue streams from additional esoteric diagnostic services Experienced team with oncology - centered genomic laboratory & clinical trial services in place

Thank You

Appendix

28 MyPRS ® Test Report ®