SECURITIES & EXCHANGE COMMISSION EDGAR FILING

SIMULATIONS PLUS INC

Form: 8-K

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

April 29, 2019
(Date of the earliest event reported)

Simulations Plus, Inc.
(Exact name of registrant as specified in its charter)

California	**001-32046**	**95-4595609**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

42505 10th Street West, Lancaster, California 93534-7059
(Address of principal executive offices) (Zip Code)

661-723-7723
Registrant's telephone number, including area code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[_] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[_] Soliciting material pursuant to Rule 14z-12 under Exchange Act (17 CFR 240.14a-12)

[_] Pre-commencement communications pursuant to Rule 14d-2(b) under Exchange Act (17 CFR 240.14d-2(b))

[_] Pre-commencement communications pursuant to Rule 13e-4(c) under Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging Growth Company [_]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [_]

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

Appointment of Director

On May 1, 2019, the Nominating Committee of Simulation Plus, Inc.'s (the "Company") Board of Directors (the "Board") nominated Dr. Lisa LaVange to the Board. The Board unanimously voted to appoint Dr. LaVange to join the Board effective May 1, 2019. She will hold this position until the next annual meeting of the Company's shareholders or until her successor is elected and qualified, subject to her earlier resignation or removal.

Dr. LaVange was chosen for her extensive expertise with biostatistics and experience with academia, commercial organizations, and government regulators, including a senior position at the U.S. Food and Drug Administration (FDA).

Dr. LaVange is expected to be named as Chairman of the Compensation Committee and a member of the Audit Committee as well as the Nominating Committee of the Board.

There is no arrangement or understanding between Dr. LaVange and any other person pursuant to which Dr. LaVange was selected as a director of the Company. Other than the Company's formal plan for compensating its directors for their services, whereby each independent director receives $2,500 per meeting of the Board attended, annual stock grants valuing $49,000, and an annual stipend of $11,000, there are no plans, contracts or arrangements or amendments to any plans, contracts or arrangements entered into with Dr. LaVange in connection with her election to the Board, nor are there any grants or awards made to Dr. LaVange in connection therewith. Dr. LaVange is not a participant in, nor is she to be a participant in, any related-person transaction or proposed related-person transaction required to be disclosed by Item 404(a) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

Resignation of Director

On April 29, 2019, Dr. Thaddeus H. Grasela, resigned as a director from the Company, effective as of April 29, 2019.

Item 7.01 Regulation FD Disclosure

On May 1, 2019, the Company announced the appointment of Dr. LaVange to the Board. A copy of the press release issued by the Company announcing Dr. LaVange's appointment is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information set forth under Item 7.01 of this Current Report on Form 8-K ("Current Report"), including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The information set forth in this Current Report shall not be deemed an admission as to the materiality of any information in this report on Current Report that is required to be disclosed solely to satisfy the requirements of Regulation FD.

This Current Report, including the disclosures set forth herein, contains certain forward-looking statements that involve substantial risks and uncertainties. When used herein, the terms "anticipates," "expects," "estimates," "believes" and similar expressions, as they relate to us or our management, are intended to identify such forward-looking statements.

Forward-looking statements in this Current Report or hereafter, including in other publicly available documents filed with the Securities and Exchange Commission (the "Commission"), reports to the shareholders of Simulations Plus, Inc., a California corporation (the "Company" or "us," "our" or "we") and other publicly available statements issued or released by us involve known and unknown risks, uncertainties and other factors which could cause our actual results, performance (financial or operating) or achievements to differ from the future results, performance (financial or operating) or achievements expressed or implied by such forward-looking statements. Such future results are based upon management's best estimates based upon current conditions and the most recent results of operations. These risks include, but are not limited to, the risks set forth herein and in such other documents filed with the Commission, each of which could adversely affect our business and the accuracy of the forward-looking statements contained herein. Our actual results, performance or achievements may differ materially from those expressed or implied by such forward-looking statements.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press release issued on May 1, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SIMULATIONS PLUS, INC.

May 1, 2019

By: */s/ Shawn O'Connor*
Shawn O'Connor
Chief Executive Officer

Exhibit 99.1

Simulations Plus, Inc.
42505 10th Street West
Lancaster, CA 93534-7059

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For Immediate Release:
May 1, 2019

Lisa LaVange, PhD, Appointed to Board of Directors of Simulations Plus

Brings 35+ Years of Industry and Regulatory Expertise to Board

Lancaster, CA, May 1, 2019 – Simulations Plus, Inc. (Nasdaq:SLP), the premier provider of simulation and modeling software and consulting services for all stages of pharmaceutical discovery and development, today announced the appointment of Dr. Lisa LaVange to the Company's Board of Directors. With a distinguished career spanning more than 35 years, Dr. LaVange brings expertise in biostatistics and experience with academia, commercial organizations, including Quintiles, the largest pharmaceutical outsourcing services company in the U.S., and government regulators, including a senior position at the U.S. Food and Drug Administration (FDA).

Dr. LaVange currently serves as Professor and Associate Chair of the Department of Biostatistics in the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill. At UNC, she directs the establishment of a new Master's in Public Health (MPH) program with a concentration in data science, and is planning a regulatory science curriculum focused on statistical methodologies in two areas: precision medicine and real-world evidence. In addition, she is currently Principal Investigator (PI) of the coordinating centers for two large and complex trial networks: the NICHD-sponsored Adolescent Medicine Trials in HIV/AIDS Interventions Network (ATN) and the NHLBI-sponsored Precision Medicine in Severe and Exacerbation-Prone Asthma Network (PreciSE).

From 2011 to 2017, Dr. LaVange served as Director of the Office of Biostatistics in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). In this role, she directed 215 statistical reviewers, analysts, and support staff involved in the development and application of statistical methodology for drug regulation. She was responsible for statistical review of all investigational drugs, therapeutic biologics, biosimilar products, and generic drugs. She also chaired the Statistical Policy Council and was a member of CDER's Medical Policy Council, setting statistical policy and overseeing statistical guidance development and publication for the Center.

Previously, she worked for six years at Quintiles, Inc. (now IQVIA), serving as Vice President of Biostatistics for her last three years. Quintiles is the largest pharmaceutical outsourcing services company in the U.S. In this role, she directed over 200 statisticians and programmers located in five offices across North America, supporting clinical trial operations, regulatory submissions, and post-marketing evaluations for a variety of large and small pharmaceutical and biotechnology companies. Dr. LaVange also served as Vice President, Biostatistics and Data Management, for Inspire Pharmaceuticals, Inc. Dr. LaVange is an elected fellow of the American Statistical Association (ASA) and was the 2018 ASA President. She is also former president of the Eastern North American Region of the International Biometric Society (ENAR-IBS) and former IBS Board member.

“For more than 35 years, I have worked with commercial organizations, academic researchers, and government regulators in areas of statistical research and methodologies, with a particular focus on biotechnology,” commented Dr. LaVange. “Throughout most of that time, Simulations Plus has been a leader in the advancement of sophisticated modeling and simulation technology in this sector. I am honored and excited to join the Board of Directors, and I look forward to helping Simulations Plus continue its growth. Technology continues to play an increasingly vital role in drug development, and I hope to accelerate adoption of *in silico* modeling as a member of the Simulations Plus Board of Directors.”

Walt Woltosz, Founder and Chairman of the Board, added: “Dr. LaVange was selected after the most exhaustive search for a new independent director in our company’s history, and we could not be more thrilled to add a leader with her broad and noteworthy expertise to our board. Her tenures at Quintiles and Inspire provide highly relevant experience to our board, enabling her to easily put herself in the position of our customers. In addition, the Board and management will benefit from her experience with the FDA, as well as her deep academic background. Concurrently, Dr. Ted Grasela has resigned from the Board. He remains Cognigen President and will continue to focus on the growth of our consulting practice and his work with key clients and the FDA. We thank Ted for his outstanding service to the Board of Directors.”

Shawn O’Connor, Chief Executive Officer of Simulations Plus, added: “Dr. LaVange adds highly relevant experience across all facets of our industry to an already strong Board of Directors. Our entire management team looks forward to benefitting from her experience and expertise.”

Dr. LaVange will serve as an independent director, with a term through the 2020 annual shareholder meeting. It is anticipated that Dr. LaVange will serve as the Chairman of the Compensation Committee and also will be a member of the nominating and audit committees.

About Simulations Plus, Inc.

Simulations Plus, Inc., is a premier developer of drug discovery and development software as well as a leading provider of both preclinical and clinical pharmacometric consulting services for regulatory submissions and quantitative systems pharmacology models for drug-induced liver injury, drug-induced kidney injury, and nonalcoholic fatty liver disease. The company is a global leader focused on improving the ways scientists use knowledge and data to predict the properties and outcomes of pharmaceutical, biotechnology, and chemical agents. Our software is licensed to and used in the conduct of drug research by major pharmaceutical, biotechnology, chemical, and consumer goods companies and regulatory agencies worldwide. Our innovations in integrating new and existing science in medicinal chemistry, computational chemistry, pharmaceutical science, biology, and physiology into our software have made us the leading software provider for physiologically based pharmacokinetic modeling and simulation. For more information, visit our website at www.simulations-plus.com.

Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995 – With the exception of historical information, the matters discussed in this press release are forward-looking statements that involve a number of risks and uncertainties. Words like “believe,” “expect” and “anticipate” mean that these are our best estimates as of this writing, but that there can be no assurances that expected or anticipated results or events will actually take place, so our actual future results could differ significantly from those statements. Factors that could cause or contribute to such differences include, but are not limited to: our ability to maintain our competitive advantages, acceptance of new software and improved versions of our existing software by our customers, the general economics of the pharmaceutical industry, our ability to finance growth, our ability to continue to attract and retain highly qualified technical staff, our ability to identify and close acquisitions on terms favorable to the Company, and a sustainable market. Further information on our risk factors is contained in our quarterly and annual reports and filed with the U.S. Securities and Exchange Commission.

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