

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): May 27, 2021

Progenity, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39334
(Commission
File Number)

27-3950390
(IRS Employer
Identification No.)

**4330 La Jolla Village Drive, Suite 200,
San Diego, CA**
(Address of Principal Executive Offices)

92122
(Zip Code)

Registrant's Telephone Number, Including Area Code: (855) 293-2639

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	PROG	The Nasdaq Global Market

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 2.05. Costs Associated with Exit or Disposal Activities

On May 27, 2021, the Board of Directors (the “Board”) of Progenity, Inc. (the “Company”), in connection with a strategic transformation of the Company, approved a plan of termination involving the termination of approximately 374 employees across the Company and its affiliated entity, Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics, which represents approximately 56% of the total workforce (the “Strategic Transformation”).

The Board approved the Strategic Transformation in an effort to materially reduce operating expenditures, more effectively allocate capital and unlock the value of the Company’s differentiated R&D pipeline. In connection with the Strategic Transformation, the Company will discontinue providing genetic laboratory-developed test services through its Ann Arbor, Michigan CLIA-certified laboratory. The Strategic Transformation is expected to take approximately 60 days to complete. The Company currently continues to offer diagnostic testing services through Avero Diagnostics. The Company’s estimated severance cost is approximately \$5 million. Other costs as a result of the Strategic Transformation, including those costs that will result in future cash expenditures, are unknown at this time. On June 2, 2021, the Company issued a press release announcing the Strategic Transformation and withdrawing its financial guidance for the remainder of 2021. A copy of this press release is filed herewith as Exhibit 99.1.

Item 8.01. Other Events

The Company expects to adjourn its 2021 Annual Meeting of Stockholders (the “Annual Meeting”) on June 2, 2021 to allow additional time for stockholders to vote on the proposals described in the proxy statement for the Annual Meeting, filed with the Securities and Exchange Commission on April 15, 2021. The adjourned Annual Meeting will be reconvened on June 14, 2021 at 11:00 a.m. Pacific Time (the “Reconvened Meeting”). The Reconvened Meeting will be held as a virtual meeting, accessible by visiting www.virtualshareholdermeeting.com/PROG2021.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements related to our expectations with respect to the Company’s planned Strategic Transformation, including the areas on which the Company intend to refocus its operations, the expected timing of completion of the Strategic Transformation, the Company’s expectations with respect to the operations of Avero Diagnostics, and the estimated severance and other costs associated with the Strategic Transformation. These forward-looking statements are based on management’s beliefs and assumptions and on information currently available to management. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. The Company does not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from the Company’s historical experience and its present expectations or projections. These risks and uncertainties include, but are not limited to, those described above and in “Item 1A. Risk Factors” and elsewhere in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 and those described from time to time in other reports which the Company files with the Securities and Exchange Commission, including but not limited to its Quarterly Reports on Form 10-Q.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibits.

99.1 [Press release, dated June 2, 2021](#)

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 hereunto duly authorized.

Date: June 2, 2021

Progenity, Inc.

By: /s/ Harry Stylli, Ph.D.
Harry Stylli, Ph.D.
Chairman and Chief Executive Officer



**Progenity Launches Strategic Transformation into Biotech Company,
Eliminating Costs of Progenity Genetics Lab and Focusing on Robust, Innovative R&D Pipeline**

Closure of genetics lab and other operational improvements expected to result in approximately 70% reduction of annual capital required for operations – from more than \$180 million currently to targeted operating expenses of ~\$50 million in 2022

Continuing to seek opportunities to generate non-dilutive capital through partnerships and strategic alternatives for non-core assets, including Avero Diagnostics, which may help fund the company

Focused on delivering on exciting 2021 and 2022 R&D pipeline with the Preecludia™ test, gastrointestinal (GI) health, and oral biopharmaceutical program milestones

Management to host webcast and conference call today at 8:30 a.m. ET / 5:30 a.m. PT

SAN DIEGO, June 2, 2021 (GLOBE NEWSWIRE) — Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, today announced a transformation strategy that will focus the company primarily on its robust R&D pipeline and better position the business for future growth. To achieve this vision, simplify its business model, and unlock shareholder value, the company will seek to reallocate resources to R&D and materially reduce operating expenditures by approximately 70%.

- **Cost Realignment.** Progenity will discontinue providing genetic laboratory-developed test services through its Ann Arbor, Michigan CLIA-certified laboratory and cease offering its Preparent® Carrier Test, Innatal® Prenatal Screen, Riscover® Hereditary Cancer Test, and Resura® Prenatal Test. This strategic transformation is expected to be completed over the next approximately 60 days and will include a reduction in force of approximately 374 employees across Progenity and Avero, or approximately 56% of its total workforce. The transformation is also expected to result in annualized cost savings of approximately \$130 million in SG&A. The company's capital requirements after accounting for the costs of the transformation are expected to be approximately \$4-5 million per month before any non-dilutive inflows.
- **Opportunities for Non-Dilutive Capital Infusion.** Progenity's in-network affiliate lab, Avero Diagnostics, is approaching operating profitability, with growing revenues projected to be \$35-40 million for 2021 derived from anatomic pathology, genetic testing and infectious diseases. Progenity is evaluating strategic opportunities for Avero to generate non-dilutive capital that may help fund the company.
- **Focus on Innovation.** Progenity's continuous pursuit of innovative solutions seeks to provide near-term commercial applications while also developing the drug delivery systems of the future, with critical near-term milestones across its Preecludia™ pre-eclampsia rule-out test, Drug Delivery System (DDS) platform, and Oral Biopharmaceuticals Delivery System (OBDS).

Drug Pipeline

- Continued development of GI-targeted therapeutics differentiated by its DDS platform for localized, topical delivery and proprietary liquid formulations designed to optimize local issue uptake. These candidates have the potential to improve efficacy, tolerability, and patient outcomes for inflammatory bowel disease – a \$15 billion market. The two lead drug DDS combinations are PGN-600 (Tofacitinib + DDS) and PGN-001 (Adalimumab + DDS), with other candidates under consideration. In the first half of 2022, the company anticipates the initiation of the first clinical study evaluating a therapeutic delivered with DDS.
- Continued development of oral biopharmaceuticals delivery system (OBDS) programs designed for optimized systemic uptake focusing on monoclonal biotherapeutics based on promising preclinical data. The lead drug-OBDS combinations, each with the potential to address markets in excess of \$1 billion, are PGN-OB1 (oral Adalimumab) for the treatment of autoimmune disorders and PGN-OB2 (oral Liraglutide) for the treatment of type 2 diabetes and cardiovascular outcomes, with other monoclonal-based biotherapeutics under consideration.

Preecludia™

- Advancement of its Preecludia™ preeclampsia rule-out test through validation and progressing physician education programs, clinical utility, health economics, and reimbursement. With topline validation anticipated in the June/July 2021 timeframe, the Preecludia™ test is expected to target an addressable market of up to \$3 billion in the U.S. alone. The Preecludia™ test, in addition to the laboratory-developed test (LDT) immunodiagnostic, has potential as an in vitro diagnostic and point-of-care solution globally. The company is exploring partnerships for these options.

Ongoing Development

- Continued development of its ingestible lab-in-a-capsule technology (PIL Dx), initially focused on small intestinal bacterial overgrowth (SIBO), an estimated \$36 billion U.S. market, and Recoverable Sample System (RSS) technologies. The RSS, when used in conjunction with targeted therapeutics, has the potential to enable the development of complementary and companion diagnostics. Key clinical milestones are expected in the next 2-3 quarters.
- Continued development of its single-molecule detection platform, the first application of which is for noninvasive prenatal testing (NIPT), with future potential applications in oncology and GI disease in support of the RSS and PIL Dx technologies. The company is progressing towards achieving initial development milestones in the next two quarters.
- **The Path Forward.** By focusing its business model, the company intends to more effectively allocate capital, reduce expenditures, and unlock the value of its highly differentiated R&D pipeline. Progenity's innovation pipeline has the potential to address markets collectively valued at greater than \$200 billion. By progressively concentrating resources on the Preecludia™ test, GI health, and oral biopharmaceuticals opportunities, Progenity hopes to unlock significant value for shareholders and improve patient outcomes.

“The strategic transformation presented today seeks to significantly reduce our burn rate by eliminating major costs and reducing our cash needs considerably to a normalized rate of \$4-5 million per month (before taking into account non-dilutive sources of capital). Our innovative R&D pipeline has always been core to our future growth plan and has the potential to transform and address significant markets by improving patient outcomes,” said Harry Stylli, PhD, CEO, Chairman of the Board of Directors, and co-founder of Progenity. “Leading with innovation also enables Progenity to exercise greater control over our costs, as a significant proportion of the company’s spend is discretionary and milestone driven. We believe that we can deploy capital more efficiently by focusing on the differentiated innovation assets in our portfolio that have the greatest potential to drive shareholder value and generate non-dilutive dollars through scalable partnerships.”

Stylli continued, “It is especially difficult to say goodbye to valued team members. We are grateful for their dedication and support over these past years. We also appreciate the healthcare providers, patients, and other stakeholders that have placed trust in us at critical life moments for more than a decade.”

As part of the strategic transformation, Progenity will continue to evaluate its operations to better position the business for future growth and continued innovation. In light of the impact of this strategic transformation, the company is withdrawing previously announced financial guidance for 2021.

Webcast and Conference Call Information

Progenity will host a webcast and conference call to discuss the strategic transformation and answer investment community questions today, Wednesday, June 2, 2021 at 8:30 a.m. ET / 5:30 a.m. PT. The live call may be accessed by dialing 833-519-1237 for domestic callers and 914-800-3810 for international callers and entering the conference code: 1285219. A live webcast and archive of the call will be available online on the investor relations section of the company website at www.progenity.com.

About Progenity

Progenity, Inc. is a biotechnology company innovating in the fields of gastrointestinal health and oral biotherapeutics. Progenity applies a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics to its molecular testing products and to the development of a suite of investigational ingestible devices designed to provide precise diagnostic sampling and drug delivery solutions. Progenity’s vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies.

For more information about Progenity’s products and pipeline visit www.progenity.com, or follow the company on [LinkedIn](#) or [Twitter](#).

Forward Looking Statements

This press release contains “forward-looking statements,” which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, including statements regarding the Company’s transformation activities and expected benefits and costs savings; potential benefits from a strategic and cost realignment, including potential future growth; potential future strategic transactions; potential addressable market sizes; our ability to deliver value for shareholders; the timing for future milestones, including the commencement of clinical trials and validation of Preecludia; the potential for our innovation pipeline; the development of our DDS and OBDS platforms; the potential benefits of the DDS and OBDS platforms; the development pipeline of therapeutic candidates that use the DDS and OBDS platforms; and the development of drug-device combination products, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “plan” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause the Company’s actual results to differ materially from the forward-looking statements expressed or implied in this press release, including: whether we will realize anticipated benefits of our strategic transformation; whether we are able to develop any products that meet our desired target product profile and address the relevant clinical need or commercial opportunity; whether any products that we develop will prove to be effective in preclinical and/or clinical trials or otherwise; whether we will obtain necessary regulatory authorizations, in a timely manner or at all; competition from existing products or new products; the timing of regulatory review and our ability to obtain regulatory marketing authorizations of our product candidates; preclinical and/or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; the ongoing COVID-19 pandemic and associated shelter-in-place orders; the loss or retirement of key scientific or management personnel; and those risks described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 18, 2021, and other subsequent documents we file with the SEC, including but not limited to our Quarterly Reports on Form 10-Q. We claim the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We expressly disclaim any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

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