Progenity Provides Corporate Update and Reports Second Quarter 2021 Financial Results

August 12, 2021

Announced successful completion of the validation study PRO-104 for the Preecludia™ rule out test for preeclampsia and achievement of the primary endpoint of the study protocol

Recently achieved promising results with the prototype autonomous Oral Biotherapeutics Delivery System in a single oral dose study in a porcine model for lead candidate PGN-OB1

Implemented cost-cutting measures expected to result in approximately $97 million of cost savings on an annual run-rate basis

Management will host conference call and webcast today at 4:30 p.m. ET/1:30 p.m. PT

SAN DIEGO, Aug. 12, 2021 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), a biotechnology company innovating in the fields of gastrointestinal health and oral biotherapeutics, today provided a corporate update and reported financial results for the second quarter ended June 30, 2021.

In the second quarter Progenity initiated a strategic transformation directed at significantly reducing its cash burn rate whilst accelerating its transition to an innovation-led biotech company focused on its oral delivery of biomolecules and its GI-IBD platforms. The company has implemented cost-cutting measures that are expected to result in cost savings of approximately $97 million on an annual run-rate basis, and it plans to continue to evaluate and implement further cost-saving measures.

The company also recently announced the successful completion of the validation study, PRO-104, for its Preecludia™ rule out test for preeclampsia. Importantly, Preecludia™ achieved the primary endpoint of the study protocol and demonstrated strong performance consistent with what was achieved in the PRO-129 verification study and pre-validation set.

Separately, during the second quarter the company initiated preclinical studies of its lead candidates PGN-OB1 (adalimumab a monoclonal) and PGN-OB2 (liraglutide, a GLP 1 agonist) utilizing for the first time its prototype autonomous Oral Biotherapeutics Delivery System (OBDS) in a swine model. Data from a recent study demonstrated that, in animals with significant drug detected, average bioavailability levels were approximately 15% with maximum levels up to 44% of IV for adalimumab following a single dose, highlighting the vast potential for this program.

"Our GI innovation pipeline is progressing with both the Oral Biotherapeutics Delivery System and the Drug Delivery System now available as fully autonomous prototype devices that will enable key studies to be performed to advance our programs and provide potential partnership opportunities. I'm also excited by the successful outcome for the Preecludia™ PRO-104 validation study results, which we expect the independent PIs to publish soon, and we are making good progress with our single molecule platform. I'm also pleased with the implementation and execution of our company transformation with substantial costs savings already being achieved and with more anticipated in the coming months. We are projecting multiple key catalysts in the next quarter and beyond, and we look forward to sharing those results in the near future," said Harry Stylli, PhD, CEO, chairman of the board, and co-founder of Progenity.

Second Quarter 2021 Results and Other Corporate Highlights

- Successful completion of the validation study for the Preecludia™ rule-out test for preeclampsia. Achieved the primary endpoint of the study protocol. Demonstrated strong performance and a high NPV consistent with what was achieved in the PRO-129 verification study and pre-validation set.

- Completed closure of Ann Arbor laboratory and refocus of resources toward innovation pipeline. Operating expenses reduction plan is on track to achieve target.

- Initiated preclinical studies of PGN-OB1 (adalimumab + OBDS) and PGN-OB2 (GLP 1 agonist + OBDS). Initial data is promising with average bioavailability of approximately 15% in animals where significant drug was detected, and reaching up to 44%. Existing pharma partnerships advancing as expected.

- Announced the formation of its Inflammatory Bowel Disease Clinical Advisory Board. The advisory board includes respected researchers and clinicians who are thought leaders in the research and treatment of inflammatory bowel disease (IBD).

- Ongoing clinical study in ulcerative colitis patients using adalimumab delivered by enema as proxy for PGN-001 (adalimumab + Drug Delivery System (DDS)). First four subjects have completed dosage regimen with promising initial results Clinical advisory board to meet next month to review data and help finalize design of the first human feasibility study delivering Humira with the DDS.

- Announced the appointment of Surbhi Sarna to its board of directors effective July 1, 2021. Ms. Sarna's medical device experience and her focus on development of strategic partnerships will prove valuable as the company advances its innovation pipeline.

- In June 2021, raised approximately $40.0 million in gross proceeds from a private placement with two leading healthcare-focused investment funds.

Second Quarter 2021 Financial Results

Comparison of Three Months Ended June 30, 2021 and March 31, 2021

Operating expenses were $36.1 million for the three months ended June 30, 2021, compared to $31.6 million for the three months ended March 31, 2021.

Net loss was $78.5 million for the three months ended June 30, 2021 and net loss per share was $1.23, compared to a net loss of $32.3 million and a net loss per share of $0.56 for the three months ended March 31, 2021.

Net loss from discontinued operations was $37.1 million for the three months ended June 30, 2021 and net loss per share for discontinued operations was $0.58, compared to a net loss from discontinued operations of $14.8 million and a net loss per share of $0.26 for the three months ended March 31, 2021.

Comparison of Three Months Ended June 30, 2021 and 2020

Operating expenses were $36.1 million for the three months ended June 30, 2021, compared to $26.5 million for the three months ended June 30, 2020.

Net loss was $78.5 million for the three months ended June 30, 2021 and net loss per share was $1.23, compared to a net loss of $53.1 million and a net loss per share of $6.11 for the three months ended June 30, 2020.

Net loss from discontinued operations was $37.1 million for the three months ended June 30, 2021 and net loss per share for discontinued operations was $0.58, compared to a net loss from discontinued operations of $20.1 million and a net loss per share of $2.31 for the three months ended June 30, 2020.

Webcast and Conference Call Information

Progenity will host a webcast and conference call to discuss the second quarter financial results and answer investment community questions today, Thursday, August 12, 2021 at 4:30 p.m. ET / 1:30 p.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: 8635609. A live webcast and archive of the call will be available online from 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 women's health, 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 additional information about Progenity, please visit the company's website at www.progenity.com.

Safe Harbor Statement or Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, 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 concerning the progress and future expectations of our research and development efforts 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 reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Such risks, uncertainties, and other factors include, among others, our ability to develop and commercialize our testing products, our ability to innovate in the field of precision medicine, our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines or at all, our plans to research, develop, and commercialize new products, the unpredictable relationship between preclinical study results and clinical study results, our expectations regarding future test volumes and revenues, our expectations regarding our in network position, anticipated capacity for our tests, our ability to raise sufficient capital to achieve our business objectives, the ongoing COVID-19 pandemic, and those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Progenity's Annual Report on Form 10-K for the period ended December 31, 2020 filed with the SEC and other subsequent documents, including Quarterly Reports, that we file with the SEC.

Progenity expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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Progenity, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended	
	June 30, 2021	March 31, 2021
Revenues	$ 463	$ 167
Cost of sales	—	—
Gross profit	463	167
Operating expenses:		
Research and development	13,401	11,673
Selling and marketing	2,006	1,858
General and administrative	20,709	18,100
Total operating expenses	36,116	31,631
Loss from operations	(35,653)	(31,464)
Interest expense	(3,502)	(3,520)
(Loss) gain on warrant liability	(5,146)	2,650
Interest and other income, net	2,901	14,873
Loss from continuing operations	(41,400)	(17,461)
Loss from discontinued operations	(37,131)	(14,803)
Net loss	$ (78,531)	$ (32,264)
Net loss per share from continuing operations, basic and diluted	$ (0.65)	$ (0.30)
Net loss per share from discontinued operations, basic and diluted	$ (0.58)	$ (0.26)
Net loss per share, basic and diluted	$ (1.23)	$ (0.56)
Weighted average number of shares outstanding used in calculating net loss per share, basic and diluted	63,942,298	57,493,800

Progenity, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,	
	2021	2020
Revenues	$ 463	$ —
Cost of Sales	—	—
Gross profit	463	—
Operating Expenses:		
Research and development	13,401	12,234
Selling and marketing	2,006	1,547
General and administrative	20,709	12,702
Total operating expenses	36,116	26,483
Loss from operations	(35,653)	(26,483)
Interest expense	(3,502)	(2,489)
Loss on warrant liability	(5,146)	—
Interest and other income (expense), net	2,901	(3,751)
Loss from continuing operations	(41,400)	(32,723)
Loss from discontinued operations	(37,131)	(20,060)
Net loss	(78,531)	(52,783)
Dividend paid to preferred shareholders	—	(268)
Net loss attributable to common stockholders	$ (78,531)	$ (53,051)
Net loss per share from continuing operations, basic and diluted	$ (0.65)	$ (3.77)
Net loss per share from discontinued operations, basic and diluted	$ (0.58)	$ (2.31)

Net loss per share attributable to common stockholders, basic and diluted	$ (1.23)	$ (6.11)
Weighted average number of shares outstanding used in calculating net loss per share, basic and diluted	63,942,298	8,687,250

Progenity, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	June 30, 2021	December 31, 2020 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 65,991	$ 91,520
Accounts receivable, net	5,047	6,634
Prepaid expenses and other current assets	13,107	8,107
Current assets of disposal group held for sale	30,181	20,077
Total current assets	114,326	126,338
Property and equipment, net	5,474	8,660
Other assets	146	169
Long-term assets of disposal group held for sale	—	19,273
Total assets	$ 119,946	$ 154,440
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 14,560	$ 12,657
Accrued expenses and other current liabilities	58,172	51,206
Current portion of mortgages payable and capital lease obligations	202	338
Current liabilities of disposal group held for sale	12,703	8,469
Total current liabilities	85,637	72,670
Mortgages payable and capital lease obligations, net of current portion	1,238	1,317
Convertible notes, net	157,533	158,886
Embedded derivative liability	388	18,370
Other long-term liabilities	14,759	8,239
Long-term liabilities of disposal group held for sale	—	1,952
Total liabilities	$ 259,555	$ 261,434
Stockholders' deficit:		
Common stock	82	59
Additional paid-in capital	531,156	452,992
Accumulated deficit	(652,069)	(541,274)
Treasury stock	(18,778)	(18,771)
Total stockholders' deficit	(139,609)	(106,994)
Total liabilities and stockholders' deficit	$ 119,946	$ 154,440

1. The condensed consolidated balance sheet data at December 31, 2020 has been derived from the audited consolidated financial statements, with adjustments to reflect the assets and liabilities held for sale.