

SERA PROGNOSTICS REPORTS FOURTH QUARTER 2023 FINANCIAL RESULTS

SALT LAKE CITY, March 20, 2024 /PRNewswire/ -- **Sera Prognostics** Inc., The Pregnancy Company® (Nasdaq: SERA), focused on improving maternal and neonatal health by providing innovative pregnancy biomarker information to doctors and patients, today announced financial results for the fourth quarter and full year ended December 31, 2023.

Recent Highlights:

- Announced that the Data Safety Monitoring Board (DSMB) overseeing Sera's pivotal [Prematurity Risk Assessment Combined with Clinical Interventions for Improved Neonatal Outcomes \(PRIME\)](#) study recommended stopping enrollment due to efficacy, reporting that either of the co-primary endpoints met the stopping criteria for statistical significance at the pre-planned interim analysis. In final stages of preparing manuscript submission to premier medical publications.
- Working diligently with guideline groups to develop appropriate implementation plans while working toward publication of the PRIME study results.
- Made continued progress in development of product pipeline and PreTRM® sample collection and assay enhancements, which will provide simpler, cheaper collection methods and more efficient lab processing, with validations nearly complete and plans to launch in the coming months across certain initial geographies.
- Engaged in focused commercial activities ahead of PRIME data to build toward greater PreTRM® test adoption expectations in 2024-2025.
- Started new initiatives to build awareness with expectant mothers and develop patient-facing products and a predictive analytics tool that can establish direct relationships with women and expand and diversify revenue opportunities.

"We are looking forward to an exciting year of developments for Sera, including publication of our PRIME study results while executing on commercial expansion and our plans to establish direct relationships with expectant mothers," said Zhenya Lindgardt, President and CEO of Sera Prognostics. "We expect these activities and advancements in our product pipeline to complement what we believe is our leading position in the area of maternal and neonatal health and pave the way for a future inflection in revenue growth."

Fourth Quarter 2023 Financial Results

Fourth quarter 2023 revenue of \$41,000 compared to \$65,000 for the same period of 2022.

Total operating expenses were \$8.9 million, down significantly from \$10.5 million for the fourth quarter of 2022.

Research and development expenses for the fourth quarter of 2023 were \$3.9 million compared to \$3.5 million for the fourth quarter of 2022 due primarily to higher clinical study costs.

Selling, general and administrative expenses for the fourth quarter of 2023 were \$5.0 million, down significantly from \$6.9 million for the fourth quarter of 2022 due primarily to steps to streamline commercial operations, better focus our commercial strategy and reduce overall operating expenses.

Net loss for the fourth quarter of 2023 was \$7.9 million compared to \$9.7 million for the same quarter a year ago.

Full Year 2023 Financial Results

Total full year 2023 revenue of \$306,000 compared to \$268,000 for the same period of 2022.

Total operating expenses were \$40.1 million, down from \$45.9 million for 2022.

Research and development expenses for 2023 were \$15.2 million compared to \$14.2 million for the prior year due primarily to higher clinical study costs.

Selling, general and administrative expenses for 2023 were \$24.7 million, down significantly from \$31.5 million for 2022 due primarily to steps to streamline commercial operations, better focus our commercial strategy and reduce overall operating expenses.

Net loss for 2023 was \$36.2 million compared to \$44.2 million for 2022.

As of December 31, 2023, the Company had cash, cash equivalents, and available-for-sale securities of approximately \$79.9 million.

Conference Call Information

Sera Prognostics will host a corresponding conference call and live webcast today to discuss fourth quarter and full year 2023 operational highlights, financial results and key topics at 5:00 p.m. Eastern Time. The Company notes that, although this will not be referred to in the prepared remarks during the call, it has posted an updated slide presentation to the investor relations page of its website at www.seraprognostics.com. Individuals interested in listening to the conference call may do so by dialing the following:

US domestic callers: (866) 218-2405

International callers: (412) 902-6607

Webcast Registration Link: <https://app.webinar.net/Za419djMmLE>

Live audio of the webcast will be available online from the Investors page of the Company's website at www.seraprognostics.com. The webcast will be archived on the Investors page and will be available for one year.

About Sera Prognostics, Inc.

Sera Prognostics is a leading health diagnostics company dedicated to improving the lives of women and babies through precision pregnancy care. Sera's mission is to provide early, pivotal pregnancy information to improve the health of mothers and newborns, resulting in reductions in the costs of healthcare delivery. Sera has a robust pipeline of innovative diagnostic tests focused on the early prediction of preterm birth risk and other complications of pregnancy. Sera's precision medicine PreTRM® Test reports to a physician the individualized risk of spontaneous premature delivery in a pregnancy, enabling earlier proactive interventions in women with higher risk. Sera Prognostics is headquartered in Salt Lake City, Utah.

About Preterm Birth

Preterm birth is defined as any birth before 37 weeks' gestation and is the leading cause of illness and death in newborns. The 2023 March of Dimes Report Card shows that, for the last five consecutive years, more than one in ten infants is born prematurely in the United States. Prematurity is associated with a significantly increased risk of major long-term medical complications, including learning disabilities, cerebral palsy, chronic respiratory illness, intellectual disability, seizures, and vision and hearing loss, and can generate significant costs throughout the lives of affected children. The annual health care costs to manage short- and long-term complications of prematurity in the United States were estimated to be approximately \$25 billion for 2016.

About the PreTRM[®] Test

The PreTRM[®] Test is the only broadly validated, commercially available blood-based biomarker test that provides an early, accurate and individualized risk prediction for spontaneous preterm birth in asymptomatic singleton pregnancies. The PreTRM[®] Test measures and analyzes proteins in the blood that are highly predictive of preterm birth. The PreTRM[®] Test permits physicians to identify, during the weeks 18 through 20 of pregnancy, which women are at increased risk for preterm birth and its complications, enabling more informed, personalized clinical decisions based on each woman's individual risk. The PreTRM[®] Test is ordered by a medical professional.

Sera Prognostics, the Sera Prognostics logo, The Pregnancy Company, and PreTRM are trademarks or registered trademarks of Sera Prognostics, Inc. in the United States and/or other countries.

Safe Harbor Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the Company being in the final stages of preparing a PRIME manuscript submission to premier medical publications; the Company working with guideline groups to develop appropriate implementation plans; sample collection and assay enhancements providing simpler, cheaper collection methods and more efficient lab processing, with validations nearly complete and plans to launch in the coming months; building toward greater PreTRM[®] test adoption expectations in 2024-2025; building awareness with expectant mothers and developing patient-facing products and a predictive analytics tool that can establish direct relationships with women and expand and diversify revenue opportunities; publication of our PRIME study results in 2024; commercial expansion; a future inflection in revenue growth; and the company's strategic directives under the caption "About Sera Prognostics, Inc." These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by forward-looking statements. These risks and uncertainties include, but are not limited to: net losses, cash generation, and the potential need to raise more capital; revenues from the PreTRM Test representing substantially all Company revenues to date; the need for broad scientific and market acceptance of the PreTRM Test; a concentrated number of material customers; our ability to introduce new products; potential competition; our proprietary biobank; critical suppliers; the COVID-19 pandemic and its potential lingering impact on our operations, as well as the business or operations of third parties with whom we conduct business; estimates of total addressable market opportunity and forecasts of market growth; potential third-party payer coverage and reimbursement; new reimbursement methodologies applicable to the PreTRM Test, including new CPT codes and payment rates for those codes; changes in FDA regulation of laboratory-developed tests; the intellectual property rights protecting our tests and market position; and other factors discussed under the heading "Risk Factors" contained in our Final Prospectus on Form S-1, which was filed with the Securities and Exchange Commission on July 14, 2021, as well as any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K, or Current Reports on Form 8-K. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information unless required by law.

SERA PROGNOSTICS, INC. Condensed Statements of Operations (unaudited)

(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue	\$ 41	\$ 65	\$ 306	\$ 268
Operating expenses:				
Cost of revenue	24	59	210	193
Research and development	3,895	3,485	15,225	14,244
Selling and marketing	1,304	3,055	8,349	14,699
General and administrative	3,666	3,884	16,343	16,784
Total operating expenses	8,889	10,483	40,127	45,920
Loss from operations	(8,848)	(10,418)	(39,821)	(45,652)
Interest expense	(11)	(18)	(55)	(61)
Other income, net	934	690	3,634	1,527
Net loss	\$ (7,925)	\$ (9,746)	\$ (36,242)	\$ (44,186)
Net loss per share, basic and diluted	\$ (0.25)	\$ (0.31)	\$ (1.16)	\$ (1.43)
Weighted-average shares of common stock outstanding, basic and diluted	31,414,446	31,017,472	31,200,652	30,943,426

SERA PROGNOSTICS, INC. Condensed Balance Sheets (unaudited) (in thousands)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,880	\$ 29,878

Marketable securities	45,199	52,826
Accounts receivable	160	113
Other receivables	11,310	6,000
Prepaid expenses and other current assets	795	1,308
Total current assets	61,344	90,125
Property and equipment, net	1,999	3,059
Long-term marketable securities	30,841	21,329
Other assets	1,257	1,816
Total assets	<u>\$ 95,441</u>	<u>\$ 116,329</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,046	\$ 1,548
Accrued and other current liabilities	2,722	4,444
Finance lease obligation, current portion	440	464
Deferred revenue	20,235	9,082
Total current liabilities	24,443	15,538
Finance lease obligation, net of current portion	196	626
Operating lease obligation, net of current portion	644	1,222
Total liabilities	25,283	17,386
Commitments and contingencies		
Stockholders' equity:		
Common stock, Class A and Class B	3	3
Additional paid-in capital	317,066	310,575
Accumulated other comprehensive loss	(15)	(981)
Accumulated deficit	(246,896)	(210,654)
Total stockholders' equity	70,158	98,943
Total liabilities and stockholders' equity	<u>\$ 95,441</u>	<u>\$ 116,329</u>

SOURCE Sera Prognostics, Inc.

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<https://investors.seraprognostics.com/2024-03-20-SERA-PROGNOSTICS-REPORTS-FOURTH-QUARTER-2023-FINANCIAL-RESULTS>