

SERA PROGNOSTICS REPORTS FOURTH QUARTER 2022 FINANCIAL RESULTS

SALT LAKE CITY, March 22, 2023 /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 2022 ended December 31, 2022.

Recent Highlights:

- Announced positive top-line results from the AVERT PRETERM TRIAL [Serum Assessment of Preterm Birth Outcomes Compared to Historical Controls](#)), conducted at ChristianaCare in Wilmington, Delaware. The results demonstrated the generalizability of the PreTRM® test-and-treat strategy in achieving meaningful clinical results in widely diverse U.S. populations toward significant improvement in neonatal health outcomes and hospital length-of-stay.
- Announced the publication of results from a clinical utility and cost-effectiveness modeling study, ACCORDANT (Analyses aCross Congruent studies ReDucing Adverse pregNancy ouTcomes), which, based on rigorous clinical utility health economic analysis, illustrated the impact of Sera's test-and-treat strategy and its specific benefits in underserved racial and ethnic populations. By combining the PreTRM® Test with enhanced prenatal care management, real progress may be possible in better serving these populations to enable better medical outcomes.
- Validated preeclampsia risk predictor, with results made available publicly and being prepared for submission to a scientific journal.
- Surpassed the required 2,800 PRIME study subject enrollment, which enables the interim look analysis by year end.

"We are pleased with the growing body of data showing the clinical utility and cost effectiveness of the PreTRM® Test in mitigating the negative health and economic consequences of preterm delivery," said Gregory C. Critchfield, MD, MS, Chairman and CEO of Sera Prognostics. "The exciting AVERT PRETERM TRIAL results are being prepared for submission to a scientific journal for publication. We believe this provides meaningful evidence of the value of our test in improving the health of moms and babies. We are excited to pursue our mission to work with doctors, patients and health systems in creating a better standard of care in pregnancies."

Fourth Quarter 2022 Financial Results

Fourth quarter 2022 revenue of \$65,000 compared to \$26,000 for the same period of 2021.

Total operating expenses were \$10.5 million, down from \$12.6 million for the fourth quarter of 2021.

Research and development expenses for the fourth quarter of 2022 were \$3.5 million compared to \$3.1 million for the fourth quarter of 2021 due primarily to increased headcount and research activities.

Selling, general and administrative expenses for the fourth quarter of 2022 were \$6.9 million, down significantly from \$9.5 million for the year-ago period due primarily to steps we took during the prior quarter to streamline our sales operations and to better focus our commercial strategy in response to market dynamics, as well as decreased administrative costs resulting from operational efficiencies.

Net loss for the fourth quarter of 2022 was \$9.7 million compared to \$12.5 million for the same quarter a year ago.

Full Year 2022 Financial Results

Total full year 2022 revenue of \$268,000 compared to \$82,000 for full year 2021.

Total operating expenses were \$45.9 million, up from \$35.5 million for 2021.

Research and development expenses for 2022 were \$14.2 million compared to \$11.0 million for the prior year due to increased clinical study costs and research activities.

Selling, general and administrative expenses for 2022 were \$31.5 million, up from \$24.4 million for the prior year due primarily to a larger sales force for the majority of the year, as well as corporate infrastructure costs related to a full year of operating as a public company.

As of December 31, 2022, the Company had cash, cash equivalents, and available-for-sale securities of approximately \$104.0 million.

Conference Call Information

Sera Prognostics will host a corresponding conference call and live webcast today to discuss fourth quarter 2022 operational highlights, financial results and key topics at 5:00 p.m. Eastern Time. 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/7E3P1Ox6ANJ>

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 located 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 2022 March of Dimes Report Card shows that, for the last four consecutive years, more than one in ten infants is born prematurely. 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 interim look analysis being enabled by year end; the growing body of data showing the clinical utility and cost effectiveness of the PreTRM® Test; the AVERT PRETERM TRIAL results being prepared for submission to a scientific journal for publication; the conference call and live webcast being held today and audio of the webcast being available on the Company's Investors page for one year; 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,	
	2022	2021	2022	2021
Revenue	\$ 65	\$ 26	\$ 268	\$ 26
Operating expenses:				
Cost of revenue	59	14	193	193
Research and development	3,485	3,075	14,244	14,244

Selling and marketing	3,055	4,548	14,699
General and administrative	3,884	4,936	16,784
Total operating expenses	10,483	12,573	45,920
Loss from operations	(10,418)	(12,547)	(45,652)
Interest expense	(18)	(2)	(61)
Other income, net	690	65	1,527
Net loss	\$ (9,746)	\$ (12,484)	\$ (44,186)
Net loss per share, basic and diluted	\$ (0.31)	\$ (0.41)	\$ (1.43)
Weighted-average shares of common stock outstanding, basic and diluted	31,017,472	30,718,121	30,943,426

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 29,878	\$ 58,932
Marketable securities	52,826	46,183
Accounts receivable	113	27
Other receivables	6,000	3,116
Prepaid expenses and other current assets	1,308	1,993
Total current assets	90,125	110,251
Property and equipment, net	3,059	1,773
Long-term marketable securities	21,329	34,848
Other assets	1,816	157
Total assets	\$ 116,329	\$ 147,029
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,548	\$ 1,197
Accrued and other current liabilities	4,444	3,885
Deferred rent, current portion	—	139
Finance lease obligation, current portion	464	74
Deferred revenue	9,082	3,116
Total current liabilities	15,538	8,411
Finance lease obligation, net of current portion	626	54
Operating lease obligation, net of current portion	1,222	—
Total liabilities	17,386	8,465
Commitments and contingencies		
Stockholders' equity:		
Common stock, Class A and Class B	3	3
Additional paid-in capital	310,575	305,212
Accumulated other comprehensive loss	(981)	(183)
Accumulated deficit	(210,654)	(166,468)
Total stockholders' equity	98,943	138,564
Total liabilities and stockholders' equity	\$ 116,329	\$ 147,029

SOURCE Sera Prognostics, Inc.

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<https://investors.seraprognostics.com/2023-03-22-SERA-PROGNOSTICS-REPORTS-FOURTH-QUARTER-2022-FINANCIAL-RESULTS>