Orchestra BioMed Reports First Quarter 2024 Financial Results and Provides a Business Update

May 13, 2024

- *Company hosting in-person R&D day event, focused on atrioventricular interval modulation ("AVIM") therapy, including the unmet need in hypertension, mechanism of action, clinical results and design of the BACKBEAT study in New York City on June 11, 2024*

NEW HOPE, Pa., May 13, 2024 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, "Orchestra BioMed" or the "Company"), a biomedical company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today reported its first quarter 2024 financial results and provided a business update.

"Since initiating patient enrollment of the BACKBEAT global pivotal study, our team has been hard at work alongside our colleagues at Medtronic to activate study sites and support patient enrollment in the U.S. and EU," commented David Hochman, founder, chief executive officer and chairman of Orchestra BioMed. "New data presented at cardiovascular medical congresses during the first quarter demonstrated AVIM therapy drove durable, long-term blood pressure reductions and exerted a favorable impact on overall cardiac hemodynamics. Seeing the mechanism of action of AVIM therapy have the therapeutic effect it is designed to in these pilot studies, not only reducing ambulatory systolic blood pressure in patients for nearly 4 years, but also enabling the heart to operate more efficiently in high-risk older patients who have a pacemaker, is encouraging as we execute the BACKBEAT pivotal study."

Mr. Hochman continued, "We see more clearly than ever the significant market opportunity for Virtue SAB following the recent FDA approval of the first drug-coated balloon for the treatment of coronary ISR. We continue to believe our highly differentiated, non-coated sirolimus-based solution offers important potential advantages to physicians and patients. We look forward to providing substantive updates on our strategic collaboration with Terumo and plans for initiating the Virtue ISR-US pivotal study in the second half of this year."

Recent Highlights

- Completed first full quarter of site activations and patient enrollment of the BACKBEAT global pivotal study evaluating the efficacy and safety of AVIM therapy in hypertensive pacemaker patients; targeting mid-2025 for completion of enrollment in collaboration with Medtronic (NYSE: MDT)
- Presented clinical results from a long-term follow-up study showing sustained reductions of 8.9 mmHg in 24-hour ambulatory systolic blood pressure ("aSBP") at a mean of 3.6 years from treatment activation in AVIM-treated patients.
- Presented clinical results evaluating the impact of AVIM therapy compared to standard pacing using invasive pressure-volume loop analysis, showing AVIM therapy had consistent favorable hemodynamic effects using both conduction system as well as traditional right ventricular lead placements and drove statistically significant reductions in systolic blood pressure, intra-cardiac volumes, total peripheral resistance, and stroke work, with no significant changes in stroke volume or contractility.
- In an upcoming R&D day event on June 11, 2024, in New York City, the Company will provide detailed overview of unmet need for better hypertension treatment in pacemaker patients, AVIM therapy mechanism of action, existing body of clinical data, and design of the BACKBEAT global pivotal study. To register, click here.

- Presented new pharmacokinetic ("PK") data at the 2024 CRT Annual Meeting demonstrating Virtue SAB enables extended release of sirolimus above required tissue concentrations in target arterial sites without polymer degradation or detectable remaining polymer within 90 days of balloon delivery.
- Appointed medical device industry expert David Pacitti, President of Siemens Medical Solutions USA, Inc. and Head of the Americas, Siemens Healthineers, to Board of Directors.

Financial Results for the First Quarter Ended March 31, 2024

- **Cash and cash equivalents and Marketable securities** totaled $75.0 million as of March 31, 2024, compared to $87.6 million as of December 31, 2023. Expected runway into second half of 2026 based on internal forecast reflecting operating priorities and certain potential future proceeds.
- **Net cash** used in operating activities and for the purchase of fixed assets was $13.1 million during the first quarter of 2024, compared with $14.4 million for the first quarter of 2023, with the primary driver of this decrease being reduced cash outflows for research and development costs and professional fees during the first quarter.
- **Revenue** for the first quarter of 2024 was $0.6 million, compared with $1.2 million for the first quarter in 2023. The decrease was primarily due to decreased recognition of partnership revenues earned under the agreement with Terumo.

- **Research and development expenses** for the first quarter of 2024 were $9.1 million, compared with $8.3 million for 2023. The increase was primarily due to additional costs associated with the ongoing BACKBEAT global pivotal study.
- **Selling, general and administrative expenses** for the first quarter of 2024 were $5.9 million, compared with $4.4 million for the first quarter of 2023. The increase was primarily due to additional personnel costs, and increased professional fees associated with being a public company.
- **Net loss** for the first quarter of 2024 was $13.5 million, or $0.38 per share, compared with a net loss of $10.9 million, or $0.40 per share, for 2023. Net loss for the first quarter of 2024 included $2.6 million in non-cash stock-based compensation expense as compared to $1.5 million for the same period in 2023.

About Orchestra BioMed

Orchestra BioMed (Nasdaq: OBIO) is a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships with leading medical device companies. Orchestra BioMed's partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. Orchestra BioMed's lead product candidate is atrioventricular interval modulation (AVIM) therapy (also known as BackBeat Cardiac Neuromodulation Therapy (CNT™)) for the treatment of hypertension, a significant risk factor for death worldwide. Orchestra BioMed is also developing the Virtue® Sirolimus AngioInfusion™ Balloon (SAB) for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Orchestra BioMed has a strategic collaboration with Medtronic, one of the largest medical device companies in the world, for development and commercialization of AVIM therapy for the treatment of hypertension in pacemaker-indicated patients, and a strategic partnership with Terumo, a global leader in medical technology, for development and commercialization of Virtue SAB for the treatment of artery disease. Orchestra BioMed has additional product candidates and plans to potentially expand its product pipeline through acquisitions, strategic collaborations, licensing and organic development. For further information about Orchestra BioMed, please visit www.orchestrabiomed.com, and follow us on LinkedIn.

References to Websites and Social Media Platforms

References to information included on, or accessible through, websites and social media platforms do not constitute incorporation by reference of the information contained at or available through such websites or social media platforms, and you should not consider such information to be part of this press release.

About AVIM Therapy (BackBeat CNT™)

AVIM therapy, also known as BackBeat CNT™, is an investigational therapy compatible with standard dual-chamber pacemakers designed to substantially and persistently lower blood pressure. It has been evaluated in pilot studies in patients with hypertension who are also indicated for a pacemaker. MODERATO II, a double-blind, randomized, pilot study, showed that patients treated with AVIM therapy experienced net reductions of 8.1 mmHg in 24-hour ambulatory systolic blood pressure (aSBP) and 12.3 mmHg in office systolic blood pressure (oSBP) at six months when compared to control patients. The global IDE BACKBEAT (BradycArdia paCemaKer with atrioventricular interval modulation for Blood prEssure treAtmenT) global pivotal study will further evaluate the safety and efficacy of AVIM therapy in lowering blood pressure in a similar target population of patients who have been indicated for, and recently implanted with, a dual-chamber cardiac pacemaker.

About Virtue SAB

Virtue SAB is a patented drug/device combination product candidate in development for the treatment of certain forms of artery disease that is designed to deliver a proprietary, investigational, extended-release formulation of sirolimus, SirolimusEFR™, to the vessel wall during balloon angioplasty without any coating on the balloon surface or the need to leave a stent or other permanent implant in the artery. Virtue SAB demonstrated positive three-year clinical data in coronary ISR in the SABRE study, a multi-center prospective, independent core lab-adjudicated clinical study of 50 patients conducted in Europe. Virtue SAB has been granted Breakthrough Device designation by the FDA for specific indications relating to coronary ISR, coronary small vessel disease and peripheral artery disease below-the-knee. The FDA granted conditional IDE approval to initiate the Virtue ISR-US study to evaluate this novel treatment in coronary ISR patients. Orchestra BioMed has a strategic partnership with Terumo (Terumo, TSE: 4543), a global leader in medical technology headquartered in Tokyo, Japan, as well as Terumo Medical Corporation, its U.S. subsidiary, to collaborate on the global development and commercialization of Virtue SAB in coronary and peripheral vascular indications.

Forward-Looking Statements

Certain statements included in this press release that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook" and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements relating to the initiation, enrollment, timing, implementation and design of the Company's planned and ongoing pivotal trials and reporting of top-line results, realizing the clinical and commercial value of BackBeat CNT and Virtue SAB, the expected runway of the Company's current cash, cash equivalents, marketable securities and expected proceeds from a revised Terumo agreement, the Company's ability to conclude a favorable collaboration agreement with Terumo, the potential safety and efficacy of the Company's product candidates, the ability of the Company's partnerships to accelerate clinical development, the Company's late-stage development programs, strategic partnerships and plans to expand its product pipeline. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the Company's management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; risks related to regulatory approval of the Company's commercial product candidates and ongoing regulation of the Company's product candidates, if approved; the timing of, and the Company's ability to achieve expected regulatory and business milestones; the impact of competitive products and product candidates; and the risk factors discussed under the heading "Item 1A. Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 27, 2024.

The Company operates in a very competitive and rapidly changing environment. New risks emerge from time to time. Given these risks and uncertainties, the Company cautions against placing undue reliance on these forward-looking statements, which only speak as of the date of this press release. The Company does not plan and undertakes no obligation to update any of the forward-looking statements made herein, except as required by law.

ORCHESTRA BIOMED HOLDINGS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 23,324	$ 30,559
Marketable securities	51,691	56,968
Strategic investments, current portion	23	68
Accounts receivable, net	67	99
Inventory	115	146
Prepaid expenses and other current assets	1,209	1,274
Total current assets	76,429	89,114
Property and equipment, net	1,309	1,279
Right-of-use assets	1,501	1,555
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	894	769
TOTAL ASSETS	$ 82,628	$ 95,212
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,354	$ 2,900
Accrued expenses and other liabilities	3,526	5,149
Operating lease liability, current portion	465	649
Deferred revenue, current portion	3,071	2,510
Total current liabilities	10,416	11,208
Deferred revenue, less current portion	13,865	14,923
Operating lease liability, less current portion	1,159	1,038
TOTAL LIABILITIES	25,440	27,169
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at March 31, 2024 and December 31, 2023.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 35,784,997 and 35,777,412 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively.	4	4
Additional paid-in capital	319,509	316,903
Accumulated other comprehensive loss	(8)	(10)
Accumulated deficit	(262,317)	(248,854)
TOTAL STOCKHOLDERS' EQUITY	57,188	68,043
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 82,628	$ 95,212

ORCHESTRA BIOMED HOLDINGS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Partnership revenue	$ 497	$ 1,019
Product revenue	123	145
Total revenue	620	1,164

Expenses:		
Cost of product revenues	34	44
Research and development	9,112	8,254
Selling, general and administrative	5,897	4,411
Total expenses	15,043	12,709
Loss from operations	(14,423)	(11,545)
Other income (expense):		
Interest income, net	1,016	885
Loss on fair value adjustment of warrant liability	—	(294)
(Loss) gain on fair value of strategic investments	(45)	14
Other expense	(11)	—
Total other income	960	605
Net loss	$ (13,463)	$ (10,940)
Net loss per share		
Basic and diluted	$ (0.38)	$ (0.40)
Weighted-average shares used in computing net loss per share, basic and diluted	35,777,877	27,643,549
Comprehensive loss		
Net loss	$ (13,463)	$ (10,940)
Unrealized gain (loss) on marketable securities	2	(27)
Comprehensive loss	$ (13,461)	$ (10,967)

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