Orchestra BioMed Reports Second Quarter 2023 Financial Results and Provides Business Update

August 10, 2023

- *U.S. Food and Drug Administration ("FDA") granted Investigational Device Exemption ("IDE") approval with conditions for Virtue SAB® coronary in-stent restenosis ("ISR") U.S. pivotal study (in collaboration with Terumo Corporation ("Terumo")); study expected to start before the end of 2023*
- *BackBeat CNT™ global pivotal study in hypertensive pacemaker patients (in collaboration with Medtronic) on track for initiation in the second half of 2023*

NEW HOPE, Pa., Aug. 10, 2023 (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 second quarter 2023 financial results and provided a business update.

"We are excited about this week's announcement of the FDA's IDE approval for our Virtue ISR-US pivotal study. This latest milestone kicks off what is expected to be a busy second half of 2023 for Orchestra BioMed, which we believe will feature the initiation of pivotal studies for both of our flagship partnered development programs. These two studies are key next steps toward realizing the substantial potential clinical and commercial value of BackBeat CNT and Virtue SAB," commented David Hochman, Chairman, Chief Executive Officer and Founder of Orchestra BioMed. "We are focused on delivering on these milestones and continuing to build upon the significant momentum from the first half of the year. To support our growth strategy, we recently entered the public markets as a Nasdaq-listed company and strengthened our leadership team with the appointments of several highly skilled senior executives. Looking ahead, we are well-funded, have outstanding partners and are well-positioned to accomplish our mission of accelerating high impact medical innovations to physicians and patients."

Pipeline highlights

- **BackBeat Cardiac Neuromodulation Therapy (CNT™) – Hypertension in Pacemaker Patients**
  - Global pivotal study evaluating the efficacy and safety of BackBeat CNT in adult patients with hypertension who are indicated for a pacemaker on track to start in the second half of 2023
- **Virtue® Sirolimus AngioInfusion™ Balloon (SAB) – Coronary Indications**
  - FDA granted IDE approval with conditions of U.S. pivotal study evaluating Virtue SAB in adult patients with coronary ISR, expected to start before the end of 2023
  - Planned Clinical Trial Notification ("CTN") submissions to the Japanese Pharmaceutical and Medical Devices Agency ("PMDA") for initiation of Japanese registrational studies of Virtue SAB in coronary small vessel disease and ISR are on track for Q4 2023

Corporate highlights

- Established new corporate development function with the appointment of Bill Little as Executive Vice President of Corporate Development and Strategy
- Appointed Andrew Taylor as Chief Financial Officer

Financial Results for the Second Quarter Ended June 30, 2023

- **Cash and cash equivalents and marketable securities** totaled $117.7 million as of June 30, 2023. Based on current clinical development, other research and development plans, and budget estimates, the Company anticipates the cash and cash equivalents and marketable securities are sufficient to fund operations into 2026.
- **Net cash** used in operating activities and for the purchase of fixed assets was $10.5 million during the second quarter of 2023, compared with $7.9 million for the same period in 2022.
- **Revenue** for the second quarter of 2023 was $0.9 million, compared with $0.4 million for the same period in 2022. The increase was primarily due to increased recognition of partnership revenues earned under the agreement with Terumo.
- **Research and development (R&D) expenses** for the second quarter of 2023 were $8.5 million, compared with $5.0 million for the same period in 2022. The increase was primarily due to additional costs associated with preparation for the initiation of the Virtue SAB and BackBeat CNT pivotal clinical studies.
- **Selling, general and administrative expenses** for the second quarter of 2023 were $5.3 million, compared with $2.9 million for the same period in 2022. The increase was primarily due to additional personnel costs, legal, insurance and finance costs, and additional costs related to being a public company.
- **Net loss** for the second quarter of 2023 was $12.0 million, or $0.35 per share, compared with a net loss of $7.8 million, or

$0.77 per share, for the same period in 2022.

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 flagship product candidates include BackBeat Cardiac Neuromodulation Therapy™ (CNT™) for the treatment of hypertension, a significant risk factor for death worldwide, and 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 BackBeat CNT 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 and Twitter.

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 BackBeat CNT

BackBeat CNT is an investigational bioelectronic treatment designed to lower blood pressure. It is compatible with standard pacemakers as a firmware upgrade and has been evaluated in pilot studies in patients with hypertension who are also indicated for pacemakers. It is estimated that more than 70% of the approximately 1.1 million people globally who are implanted with cardiac pacemakers each year are also diagnosed with hypertension[1].

The peer-reviewed, double-blind, randomized pilot study, MODERATO II, showed that patients treated with BackBeat CNT 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) when compared to control patients at six months. Orchestra BioMed plans to conduct a global pivotal study to further evaluate the safety and efficacy of BackBeat CNT in lowering blood pressure in a similar target population of patients who have been indicated for, and recently received, a cardiac pacemaker implant. The strategic collaboration with Medtronic will provide Orchestra BioMed with development, clinical, and regulatory support for this planned global study. Upon regulatory approval, Medtronic will have the global rights to commercialize BackBeat CNT-enabled pacing systems for this target population. Orchestra BioMed will share in the revenues generated from Medtronic sales of the BackBeat CNT-enabled pacing systems.

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.

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 FDA's conditional approval of the Virtue ISR-US pivotal study, the initiation and timing of the Company's planned pivotal trials, realizing the clinical and commercial value of BackBeat CNT and Virtue SAB, the expected runway of the Company's current cash and cash equivalents, the potential efficacy of the Company's product candidates, the ability of the Company's partnerships to accelerate clinical development, and 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; failure to realize the anticipated benefits of the business combination; risks related to regulatory approval of the Company's product candidates; 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 quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission on May 12, 2023 as updated by any risk factors disclosed under the heading "Item 1A. Risk Factors" in the Company's subsequently filed quarterly reports on Form 10-Q.

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.

References

1. Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES).

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

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 16,409	$ 19,784
Marketable securities	101,295	63,915
Strategic investments, current portion	69	86
Accounts receivable, net	171	96
Inventory	178	276
Prepaid expenses and other current assets	1,468	533
Total current assets	119,590	84,690
Property and equipment, net	1,407	1,489
Right-of-use assets	1,874	2,187
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	517	4,711
TOTAL ASSETS	$ 125,883	$ 95,572
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,011	$ 3,968
Accrued expenses and other liabilities	3,826	5,376
Operating lease liability, current portion	729	697
Warrant liability	—	2,089
Deferred revenue, current portion	4,294	6,436
Total current liabilities	11,860	18,566
Deferred revenue, less current portion	13,498	13,103
Loan payable	9,563	9,490
Operating lease liability, less current portion	1,310	1,683
Other long-term liabilities	213	196
TOTAL LIABILITIES	36,444	43,038
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at June 30, 2023 and December 31, 2022.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 35,743,007 and 20,187,850 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively.	4	2
Additional paid-in capital	312,251	252,274
Accumulated other comprehensive loss	(96)	(8)
Accumulated deficit	(222,720)	(199,734)
TOTAL STOCKHOLDERS' EQUITY	89,439	52,534
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 125,883	$ 95,572

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

	Three Months Ended June 30,	
	2023	2022
Revenue:		
Partnership revenue	$ 728	$ 229
Product revenue	187	172
Total revenue	915	401

Expenses:		
Cost of product revenues	54	60
Research and development	8,499	5,029
Selling, general and administrative	5,318	2,946
Total expenses	13,871	8,035
Loss from operations	(12,956)	(7,634)
Other income (expense):		
Interest income (expense), net	941	(246)
Loss on fair value adjustment of warrant liability	—	(1,015)
Loss on debt extinguishment	—	(682)
(Loss) gain on fair value of strategic investments	(31)	1,730
Total other income (expense)	910	(213)
Net loss	$ (12,046)	$ (7,847)
Net loss per share		
Basic and diluted	$ (0.35)	$ (0.77)
Weighted-average shares used in computing net loss per share, basic and diluted	34,613,466	10,138,169
Comprehensive loss		
Net loss	$ (12,046)	$ (7,847)
Unrealized loss on marketable securities	(61)	—
Comprehensive loss	$ (12,107)	$ (7,847)

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