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

August 12, 2024

NEW HOPE, Pa., Aug. 12, 2024 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, “Orchestra BioMed” or the “Company”), a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships, today reported its second quarter 2024 financial results and provided a business update.

"Our work in hypertension and coronary artery disease aligns with a renaissance occurring in cardiac pacing and balloon angioplasty, applying new innovations to enhance these foundational device-based interventions and create more potent therapeutic solutions. At our inaugural R&D day in June, we were excited to share our insights into this renaissance and the potential role we believe our lead programs – AVIM therapy and Virtue SAB – will play in improving outcomes for patients. We were delighted to host esteemed cardiology leaders Drs. David Kandzari and Vivek Reddy, who highlighted the critical unmet needs in high-risk hypertension and expressed their enthusiasm for the potential of AVIM therapy to transform care for these patient populations," stated David Hochman, founder, chief executive officer, and chairman of Orchestra BioMed. "As we look ahead to the second half of the year, we remain focused on driving patient enrollment in the BACKBEAT global pivotal study across the U.S. and EU, and look forward to providing key updates on our Virtue SAB program.”

Second Quarter 2024 and Recent Business Update

During its June 11th R&D Day, Orchestra BioMed provided an educational program on its lead asset, atrioventricular interval modulation (“AVIM”) therapy for the treatment of hypertension in high-risk patient populations. Orchestra BioMed has a strategic collaboration with Medtronic (NYSE: MDT) for the development and commercialization of AVIM therapy for the treatment of hypertension in patients indicated for a cardiac pacemaker. The replay of the webcast is available on the Orchestra BioMed website: link to webcast.

The event featured presentations from key opinion leaders, David Kandzari, M.D., FACC, MSCAI and Vivek Reddy, M.D., focused on the unmet hypertension treatment need in older high-risk patients, the AVIM therapy mechanism of action, clinical data from the MODERATO I and II studies, and design of the BACKBEAT study.

R&D Day Takeaways:

- **Cardiac pacing and balloon angioplasty are undergoing a renaissance:** After decades of use in cardiovascular care, these foundational device-based interventions are evolving with the application of new therapies, like AVIM therapy and Virtue® Sirolimus AngioInfusion Balloon (“SAB”), that have the potential to substantially improve clinical outcomes in the treatment of hypertension and artery disease.
- **There is a significant unmet hypertension treatment need in older high-risk patients**: Dr. Kandzari stated that despite the significant risks associated with uncontrolled hypertension, “nearly 75% of individuals in this country alone with hypertension do not achieve societal or guideline recommended treatment goals for the management of their blood pressure.”
- **Clinical and non-clinical evidence support the proposed AVIM therapy mechanism of action**: Dr. Reddy explained how programmed pacing that modulates between short AV intervals and longer AV intervals is designed to utilize well-established cardiology principles to reduce blood pressure.
- **Clinical evidence from the MODERATO I and II studies demonstrate AVIM therapy substantially, immediately, and persistently reduced blood pressure**: Dr. Reddy described the robust body of existing clinical data from the MODERATO I and II studies as “strong evidence” that this investigative therapy may be helpful in reducing blood pressure.
- **The BACKBEAT global pivotal study is rigorously designed to generate important safety and efficacy data for AVIM therapy in pacemaker-indicated patients with uncontrolled hypertension**: Dr. Kandzari detailed the design and rationale of the BACKBEAT study, including the double-blind, randomized study's 3-month primary efficacy and safety endpoints, additional and secondary endpoints, and novel patient enrollment pathways.

Additional Recent Highlights:

- Continued focus on site activations and patient enrollment of the BACKBEAT study.
- Company remains on track to provide strategic, clinical and regulatory updates on its Virtue SAB program in the second half of 2024.
- Appointed cardiovascular device industry expert John Mack, former President and General Manager of Cardiac Surgery at Medtronic, to the Board of Directors.

Financial Results for the Second Quarter Ended June 30, 2024

- **Cash and cash equivalents and Marketable securities** totaled $65.2 million as of June 30, 2024. Cash and cash equivalents increased in July 2024 by $15 million from net cash proceeds from the sale of Company Common Stock to a single institutional investor under the Open Market Sale Agreement. Expected operating cash 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 $10.3 million during the second quarter of 2024, compared with $10.5 million for the second quarter of 2023, with the primary driver of this decrease being reduced cash outflows for research and development during the second quarter.
- **Revenue** for the second quarter of 2024 was $0.8 million, compared with $0.9 million for the second 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 second quarter of 2024 were $11.1 million, compared with $8.5 million for the same period in 2023. The increase was primarily due to additional costs associated with the ongoing BACKBEAT global pivotal study.
- **Selling, general and administrative expenses** for the second quarter of 2024 were $6.5 million, compared with $5.3 million for the second quarter of 2023. The increase was primarily due to additional personnel, legal, insurance, finance and regulatory costs.
- **Net loss** for the second quarter of 2024 was $16.0 million, or $0.45 per share, compared with a net loss of $12.0 million, or $0.35 per share, for 2023. Net loss for the second quarter of 2024 included non-cash stock-based compensation expense of $2.8 million as compared with $1.7 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. 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

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 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 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 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 and the ability of the Company's partnerships to accelerate clinical development. 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)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 23,713	$ 30,559
Marketable securities	41,468	56,968
Strategic investments, current portion	—	68
Accounts receivable, net	80	99
Inventory	70	146
Prepaid expenses and other current assets	1,150	1,274
Total current assets	66,481	89,114
Property and equipment, net	1,235	1,279
Right-of-use assets	1,331	1,555
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	841	769
TOTAL ASSETS	$ 72,383	$ 95,212
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,273	$ 2,900
Accrued expenses and other liabilities	4,225	5,149
Operating lease liability, current portion	350	649
Deferred revenue, current portion	3,656	2,510
Total current liabilities	14,504	11,208
Deferred revenue, less current portion	12,652	14,923
Operating lease liability, less current portion	1,102	1,038
TOTAL LIABILITIES	28,258	27,169
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at June 30, 2024 and December 31, 2023.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 35,824,571 and 35,777,412 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively.	4	4
Additional paid-in capital	322,441	316,903
Accumulated other comprehensive loss	(23)	(10)
Accumulated deficit	(278,297)	(248,854)
TOTAL STOCKHOLDERS' EQUITY	44,125	68,043
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 72,383	$ 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 June 30,	
	2024	**2023**
Revenue:		
Partnership revenue	$ 628	$ 728
Product revenue	150	187
Total revenue	778	915
Expenses:		
Cost of product revenues	44	54
Research and development	11,126	8,499
Selling, general and administrative	6,467	5,318
Total expenses	17,637	13,871
Loss from operations	(16,859)	(12,956)
Other income (expense):		
Interest income, net	902	941
Loss on fair value of strategic investments	(23)	(31)
Total other income	879	910
Net loss	$ (15,980)	$ (12,046)
Net loss per share		
Basic and diluted	$ (0.45)	$ (0.35)
Weighted-average shares used in computing net loss per share, basic and diluted	35,800,273	34,613,466
Comprehensive loss		
Net loss	$ (15,980)	$ (12,046)
Unrealized loss on marketable securities	(15)	(61)
Comprehensive loss	$ (15,995)	$ (12,107)

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