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

November 12, 2024

NEW HOPE, Pa., Nov. 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 third quarter 2024 financial results and provided a business update.

"The Orchestra BioMed team is focused on execution of the BACKBEAT global pivotal study alongside our strategic partner, Medtronic. We are excited about the enthusiasm we have seen from the clinical community for the potential of AVIM therapy to provide these typically older, higher risk hypertension patients with a potent, programmable, always on treatment option for managing their blood pressure,” commented David Hochman, Chairman, Chief Executive Officer, and Founder of Orchestra BioMed. “We received FDA approval for and recently started to implement an important amendment to our study protocol that improves patient engagement processes and significantly expands our window for screening and enrollment. We believe this amendment will help us execute the ongoing study and deliver regulatory-submission-ready clinical results to our partners at Medtronic.”

Mr. Hochman continued, “In parallel with our work on AVIM therapy, we are continuing to advance our Virtue SAB program with active preparations to initiate coronary pivotal studies. The agenda at this year’s TCT conference highlighted the growing importance of drug-coated balloons in the future of coronary and peripheral interventions for artery disease. We view Virtue SAB as a revolutionary innovation that can elevate this rapidly accelerating therapeutic trend, offering superior drug delivery without the limitations of fragile balloon coatings. Overall, we expect 2025 to be a milestone year for Orchestra BioMed and remain steadfast in our commitment to employ our partnership-enabled business model to deliver innovative solutions that will make a meaningful impact on patient care."

Recent Business Highlights:

- Continued site activation and patient enrollment of the BACKBEAT global pivotal study, in collaboration with Medtronic (NYSE: MDT), evaluating the efficacy and safety of atrioventricular interval modulation (“AVIM”) therapy in hypertensive pacemaker patients.
- Received FDA approval for and are now implementing an amendment to the BACKBEAT study protocol intended to improve patient engagement processes and expand the window for screening and enrolling patients.
- Preparing to initiate coronary pivotal studies for Virtue® Sirolimus AngioInfusion™ Balloon (“SAB”).
- Actively engaged with Terumo in Virtue SAB partnership restructuring discussions.
- Vivasure Medical Ltd. (“Vivasure”), a strategic holding of Orchestra BioMed, reported positive data from its U.S. IDE PATCH pivotal study at the Transcatheter Cardiovascular Therapeutics (“TCT”) 2024 annual conference demonstrating that its PerQseal® Closure Device achieved closure with very low rates of major vascular complications and rapid times to hemostasis. This data positions PerQseal for potential regulatory approval and commercial launch in 2025.
    - Haemonetics Corporation (NYSE: HAE) has invested over $30 million in Vivasure and has an option to acquire the company.

Financial Results for the Third Quarter Ended September 30, 2024

- **Cash and cash equivalents and Marketable securities** totaled $66.9 million as of September 30, 2024. Following the close of Q3 2024, cash and cash equivalents increased in November 2024 by approximately $15 million from the initial draw on our credit facility with Hercules Capital, Inc. Operating cash runway is expected 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 $13.8 million during the third quarter of 2024, compared with $10.3 million for the third quarter of 2023, with the primary driver of this increase being increased cash outflows for research and development during the third quarter of 2024.
- **Revenue** for the third quarter of 2024 was $1.0 million, compared with $0.4 million for the third quarter in 2023. The increase was primarily due to increased recognition of partnership revenues earned under the agreement with Terumo.
- **Research and development expenses** for the third quarter of 2024 were $11.6 million, compared with $8.6 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 third quarter of 2024 were $5.7 million, compared with $6.3 million for the third quarter of 2023. The decrease was primarily due to reduced expenses related to stock-based compensation.
- **Net loss** for the third quarter of 2024 was $15.4 million, or $0.41 per share, compared with a net loss of $13.3 million, or $0.38 per share, for 2023. Net loss for the third quarter of 2024 included non-cash stock-based compensation expense of

$2.4 million as compared with $3.5 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. 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 the Company's ability to restructure its partnership agreement with Terumo, the potential safety and efficacy of the Company's product candidates, regulatory approval Vivasure's PerQseal® Closure Device and the timing of any acquisition of Vivasure, *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 Securities and Exchange Commission ("SEC") on March 27, 2024 , and under the heading "Item1A. Risk Factors" in Part II of the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 12, 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)

	September 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 25,605	$ 30,559
Marketable securities	41,321	56,968
Strategic investments, current portion	—	68
Accounts receivable, net	115	99
Inventory	234	146
Prepaid expenses and other current assets	1,278	1,274
Total current assets	68,553	89,114
Property and equipment, net	1,254	1,279
Right-of-use assets	1,714	1,555
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	1,303	769
TOTAL ASSETS	$ 75,319	$ 95,212
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,723	$ 2,900
Accrued expenses and other liabilities	7,034	5,149
Operating lease liability, current portion	395	649
Deferred revenue, current portion	4,066	2,510
Total current liabilities	16,218	11,208
Deferred revenue, less current portion	11,439	14,923
Operating lease liability, less current portion	1,443	1,038
TOTAL LIABILITIES	29,100	27,169
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at September 30, 2024 and December 31, 2023.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 37,942,905 and 35,777,412 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively.	4	4
Additional paid-in capital	339,840	316,903
Accumulated other comprehensive income (loss)	98	(10)
Accumulated deficit	(293,723)	(248,854)
TOTAL STOCKHOLDERS' EQUITY	46,219	68,043
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 75,319	$ 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 September 30,	
	2024	2023
Revenue:		
Partnership revenue	$ 803	$ 271
Product revenue	184	148
Total revenue	987	419
Expenses:		
Cost of product revenues	68	41
Research and development	11,595	8,558
Selling, general and administrative	5,666	6,344

Total expenses	17,329	14,943
Loss from operations	(16,342)	(14,524)
Other income (expense):		
Interest income, net	916	915
Gain (loss) on fair value of strategic investments	—	293
Total other income	916	1,208
Net loss	$ (15,426)	$ (13,316)
Net loss per share		
Basic and diluted	$ (0.41)	$ (0.38)
Weighted-average shares used in computing net loss per share, basic and diluted	37,621,495	35,243,598
Comprehensive loss		
Net loss	$ (15,426)	$ (13,316)
Unrealized gain (loss) on marketable securities	121	19
Comprehensive loss	$ (15,305)	$ (13,297)