Orchestra BioMed Reports Second Quarter 2025 Financial Results and Highlights Recent Business Updates

August 12, 2025

- *Secured over $111 million in proceeds and committed capital following completion of strategic transactions and concurrent public and private equity offerings, led by over $71 million in committed capital from Medtronic and Ligand*
- *Achieved multiple FDA regulatory milestones: Breakthrough Device Designation for AVIM therapy; approval for expanded BACKBEAT study enrollment criteria, and IDE approval for a U.S. pivotal Virtue SAB trial versus commercially available paclitaxel-coated balloon*

NEW HOPE, Pa., Aug. 12, 2025 (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 announced financial results for the second quarter ended June 30, 2025, and provided a business update highlighting recent financial and regulatory milestones.

Q2 2025 and Recent Business Highlights:

- **Completed multiple strategic transactions and concurrent public and private equity offerings totaling an expected $111.2 million in gross proceeds** to support continued advancement of the Company's late-stage atrioventricular interval modulation ("AVIM") therapy and Virtue Sirolimus AngioInfusion Balloon ("SAB") clinical programs. Gross proceeds are comprised of:
  - $55 million received or to be received by May 1, 2026, subject to certain conditions, from royalty-based, non-dilutive investments from Ligand Pharmaceuticals Incorporated (Nasdaq: LGND, "Ligand") and Medtronic, plc (NYSE: MDT, "Medtronic")
    - Ligand committed $35 million in exchange for a tiered revenue interest in Orchestra BioMed's future royalties from AVIM therapy and Virtue SAB
    - Medtronic committed $20 million in exchange for a secured subordinated promissory note convertible to capped prepaid revenue share
  - $56.2 million received from a $40 million underwritten public offering of common stock and prefunded warrants and $11.2 million and $5 million received from private placements of common stock to Medtronic and Ligand, respectively
  - Proceeds expected to extend cash runway into the second half of 2027, supporting potentially significant value-creating catalysts, including:
    - BACKBEAT study enrollment completion in mid-2026
    - BACKBEAT study primary endpoint data
    - Substantial enrollment of the Virtue Trial
- **Medtronic and Orchestra BioMed expanded strategic collaboration** to provide pathway for future development of AVIM therapy-enabled leadless pacemakers.
- **U.S. Food and Drug Administration ("FDA") Breakthrough Device Designation ("BDD")** granted for atrioventricular interval modulation ("AVIM") therapy in patients with uncontrolled hypertension and increased cardiovascular risk, marking a major regulatory validation of the therapy's potential to improve hypertensive heart disease outcomes.
- **FDA-approved updated BACKBEAT study protocol** now being implemented, broadening patient enrollment criteria for a more than 24-fold increase in the potentially eligible patient pool; full implementation to be completed in Q4 2025.
- **FDA Investigational Device Exemption ("IDE") Approval** received for the Virtue SAB U.S. pivotal trial, a randomized head-to-head study comparing Virtue SAB with the commercially available AGENT™ DCB paclitaxel-coated balloon (the "Virtue Trial"). Trial initiation is currently targeted for the second half of 2025.
  - Orchestra BioMed is sponsoring and in full operational control of the Virtue Trial; mediation with Terumo of certain other contractual terms is progressing, with conclusion of formal mediation process expected in Q3 2025.
- **Intellectual Property Expansion** continued with AVIM therapy patent estate reaching 137 issued patents worldwide, with recent additions bolstering coverage for both hypertension and heart failure indications.

Chairman and Chief Executive Officer ("CEO") Commentary from David Hochman:

Mr. Hochman stated: "The successful completion of strategic financing transactions with Medtronic and Ligand, along with closing our first underwritten public offering are expected to give us up to $111 million in new capital to support execution of both AVIM therapy and Virtue SAB pivotal clinical studies. Our entire organization is focused on our mission to bring these high-impact, innovative, device-based therapies to market."

Mr. Hochman continued: "We were also proud to have achieved multiple key regulatory milestones for both AVIM therapy and Virtue SAB in the second quarter. The FDA Breakthrough Device Designation awarded to AVIM therapy for the treatment of uncontrolled hypertension in patients with increased cardiovascular risk has potentially significant implications to future regulatory submissions and opens up potential pathways for enhanced reimbursement for AVIM therapy-enabled devices. The FDA also approved an important update to the BACKBEAT study protocol that we are now rolling out to study centers that significantly expands eligibility criteria for enrollment and supports our enrollment completion objectives for next year. Finally, FDA approval of the updated IDE for our head-to-head pivotal trial comparing Virtue SAB to commercially available AGENT paclitaxel-coated balloon marks another significant regulatory milestone. These achievements will help us in our continued efforts to reshape clinical standards of care in both hypertensive heart disease and atherosclerotic artery disease."

Financial Results for the Second Quarter Ended June 30, 2025

- **Cash and cash equivalents and Marketable securities** totaled $33.9 million as of June 30, 2025. Combined with net proceeds received from recent financing transactions, estimated Cash and cash equivalents and Marketable securities position was $101 million as of August 12, 2025. The Company has commitments from Ligand and Medtronic to receive a combined $35 million in additional proceeds on or before May 1, 2026, based on the terms of agreements with those parties.
- **Net cash used in operating activities and for the purchase of fixed assets** was $15.6 million during the second quarter of 2025, compared with $10.3 million for the second quarter in 2024, with the primary driver being increased research and development costs during the second quarter of 2025.
- **Revenue** for the second quarter of 2025 was $0.8 million, compared with $0.8 million for the second quarter in 2024.
- **Research and development expenses** for the second quarter of 2025 were $13.9 million, compared with $11.1 million for the second quarter in 2024. 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 2025 were $6.3 million, compared with $6.5 million for the second quarter of 2024. The decrease was primarily due to a decrease in professional fees.
- **Net loss** for the second quarter of 2025 was $19.4 million, or $0.50 per share, compared with a net loss of $16.0 million, or $0.45 per share, for the second quarter of 2024. Net loss for the second quarter of 2025 included $3.2 million in non-cash stock-based compensation expense as compared to $2.8 million for the same period in 2024.

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 AVIM therapy for the treatment of hypertension, the leading risk factor for death worldwide. Orchestra BioMed is also developing Virtue 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. The Company has received four Breakthrough Device Designations from the U.S. FDA across these two core programs, reflecting the significant potential of its technologies to address high unmet needs in cardiovascular care. 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 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. In addition to reducing blood pressure, clinical results using AVIM therapy demonstrate improvements in cardiac function and hemodynamics. The BACKBEAT (BradycArdia paCemaKer with atrioventricular interval modulation for Blood prEssure treAtmenT) global pivotal study will evaluate the safety and efficacy of AVIM therapy in lowering blood pressure in patients who have systolic blood pressure above target despite anti-hypertensive medication and who are indicated for or have recently received a dual-chamber cardiac pacemaker. AVIM therapy has been granted Breakthrough Device Designation by the FDA for the treatment of uncontrolled hypertension in patients who have increased cardiovascular risk.

About Virtue SAB

Virtue SAB is an investigational therapeutic combination drug-device designed to deliver a proprietary extended-release

formulation of sirolimus, SirolimusEFR™ through a non-coated microporous AngioInfusion™ Balloon, protecting the drug in transi through the arteries and consistently delivering a large liquid dose, overcoming certain limitations of drug-coated balloons. SirolimusEFR delivered by Virtue SAB has been shown in published preclinical series involving hundreds of arterial deliveries to achieve sustained tissue levels well above the known required therapeutic tissue concentration for inhibiting restenosis (1 ng/mg tissue) for the entire critical healing period of approximately 30 days. Virtue SAB demonstrated positive three-year clinical data in coronary in-stent restenosis ("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. The FDA granted IDE approval for Orchestra BioMed to evaluate the efficacy and safety of Virtue SAB in the Virtue Trial, a pivotal trial that will randomize Virtue SAB against commercially available AGENT™ DCB, a paclitaxel-coated balloon.

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, including the timing of completion of enrollment in the BACKBEAT study and the timing of initiation of the Virtue Trial, the receipt of committed capital, the Company's expected cash runway, the date of completion of the formal mediation with Terumo, the potential benefits of BDD, realizing the clinical and commercial value of AVIM therapy and Virtue SAB, 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, 2024, which was filed with the SEC on March 31, 2025 and the risk factor discussed under the heading "Item 1A. Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, which was filed with the SEC on May 12, 2025.

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.

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

	June 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 18,749	$ 22,261
Marketable securities	15,175	44,551
Accounts receivable, net	83	92
Inventory	185	173
Prepaid expenses and other current assets	1,690	2,094

Total current assets	35,882	69,171
Property and equipment, net	1,366	1,384
Right-of-use assets	1,806	2,103
Strategic investments	2,495	2,495
Deposits and other assets	1,276	1,020
TOTAL ASSETS	$ 42,825	$ 76,173
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,308	$ 5,134
Accrued expenses and other liabilities	6,650	6,084
Operating lease liability, current portion	642	550
Deferred revenue, current portion	4,461	4,439
Total current liabilities	17,061	16,207
Deferred revenue, less current portion	9,568	10,989
Loan payable	14,384	14,292
Operating lease liability, less current portion	1,328	1,687
Other long-term liabilities	189	40
TOTAL LIABILITIES	42,530	43,215
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at June 30, 2025 and December 31, 2024.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 38,643,553 and 38,194,442 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively.	4	4
Additional paid-in capital	348,271	342,780
Accumulated other comprehensive income	16	52
Accumulated deficit	(347,996)	(309,878)
TOTAL STOCKHOLDERS' EQUITY	295	32,958
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 42,825	$ 76,173

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,	
	2025	**2024**
Revenue:		
Partnership revenue	$ 667	$ 628
Product revenue	169	150
Total revenue	836	778
Expenses:		
Cost of product revenues	46	44
Research and development	13,853	11,126
Selling, general and administrative	6,264	6,467
Total expenses	20,163	17,637
Loss from operations	(19,327)	(16,859)
Other (expense) income:		
Interest (expense) income, net	(36)	902
Loss on fair value of strategic investments	-	(23)
Total other (expense) income	(36)	879
Net loss	$ (19,363)	$ (15,980)

Net loss per share		
Basic and diluted	$ (0.50)	$ (0.45)
Weighted-average shares used in computing net loss per share, basic and diluted	38,392,716	35,800,273
Comprehensive loss		
Net loss	$ (19,363)	$ (15,980)
Unrealized loss on marketable securities	(21)	(15)
Comprehensive loss	$ (19,384)	$ (15,995)