SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 13D

Under the Securities Exchange Act of 1934

Braveheart Bio, Inc.

(Name of Issuer)

Common Stock

(Title of Class of Securities)

(CUSIP Number)

OrbiMed Advisors LLC
601 Lexington Avenue, 54th Floor
New York, NY, 10022
(212) 739-6400

OrbiMed Capital GP IX LLC
601 Lexington Avenue, 54th Floor
New York, NY, 10022
(212) 739-6400

OrbiMed Genesis GP LLC
601 Lexington Avenue, 54th Floor
New York, NY, 10022
(212) 739-6400

(Name, Address and Telephone Number of Person Authorized to Receive Notices and Communications)

08/07/2026

(Date of Event Which Requires Filing of This Statement)

If the filing person has previously filed a statement on Schedule 13G to report the acquisition that is the subject of this Schedule 13D, and is filing this schedule because of §§ 240.13d-1(e), 240.13d-1(f) or 240.13d-1(g), check the following box. ☐

The information required on the remainder of this cover page shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934 (“Act”) or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

SCHEDULE 13D

CUSIP No.

1	Name of reporting person ORBIMED ADVISORS LLC
2	Check the appropriate box if a member of a Group (See Instructions) ☐ (a) ☐ (b)
3	SEC use only
4	Source of funds (See Instructions) AF
5	Check if disclosure of legal proceedings is required pursuant to Items 2(d) or 2(e) ☐
6	Citizenship or place of organization DELAWARE
Number of Shares Beneficially Owned by Each Reporting Person With:	7 Sole Voting Power 0.00 8 Shared Voting Power 12,175,159.00 9 Sole Dispositive Power 0.00 10 Shared Dispositive Power 12,175,159.00
11	Aggregate amount beneficially owned by each reporting person 12,175,159.00
12	Check if the aggregate amount in Row (11) excludes certain shares (See Instructions) ☐
13	Percent of class represented by amount in Row (11) 17.2 %
14	Type of Reporting Person (See Instructions) IA

SCHEDULE 13D

CUSIP No.

1	Name of reporting person OrbiMed Capital GP IX LLC
2	Check the appropriate box if a member of a Group (See Instructions) ☐ (a) ☐ (b)
3	SEC use only
4	Source of funds (See Instructions)

	AF		
5	Check if disclosure of legal proceedings is required pursuant to Items 2(d) or 2(e) ☐		
6	Citizenship or place of organization DELAWARE		
Number of Shares Beneficially Owned by Each Reporting Person With:	7	Sole Voting Power 0.00	
	8	Shared Voting Power 11,901,826.00	
	9	Sole Dispositive Power 0.00	
	10	Shared Dispositive Power 11,901,826.00	
11	Aggregate amount beneficially owned by each reporting person 11,901,826.00		
12	Check if the aggregate amount in Row (11) excludes certain shares (See Instructions) ☐		
13	Percent of class represented by amount in Row (11) 16.9 %		
14	Type of Reporting Person (See Instructions) OO		

SCHEDULE 13D

CUSIP No.

1	Name of reporting person OrbiMed Genesis GP LLC		
2	Check the appropriate box if a member of a Group (See Instructions) ☐ (a) ☐ (b)		
3	SEC use only		
4	Source of funds (See Instructions) AF		
5	Check if disclosure of legal proceedings is required pursuant to Items 2(d) or 2(e) ☐		
6	Citizenship or place of organization DELAWARE		
Number of Shares Beneficially Owned by Each Reporting	7	Sole Voting Power 0.00	
	8	Shared Voting Power 273,333.00	

Person With:	9	Sole Dispositive Power 0.00
	10	Shared Dispositive Power 273,333.00

11	Aggregate amount beneficially owned by each reporting person 273,333.00
12	Check if the aggregate amount in Row (11) excludes certain shares (See Instructions) ☐
13	Percent of class represented by amount in Row (11) 0.4 %
14	Type of Reporting Person (See Instructions) OO

SCHEDULE 13D

Item 1. Security and Issuer

(a) Title of Class of Securities:

Common Stock

(b) Name of Issuer:

Braveheart Bio, Inc.

(c) Address of Issuer's Principal Executive Offices:

One Letterman Dr., Bldg. A, Ste. A4-300, San Francsico, CALIFORNIA , 94129.

Item 2. Identity and Background

(a) OrbiMed Advisors LLC ("OrbiMed Advisors") is a limited liability company organized under the laws of Delaware and a registered investment adviser under the Investment Advisers Act of 1940, as amended. OrbiMed Capital GP IX LLC ("OrbiMed GP") is a limited liability company organized under the laws of Delaware. OrbiMed Genesis GP LLC ("OrbiMed Genesis" and together with OrbiMed Advisors and OrbiMed GP, the "Reporting Persons") is a limited liability company organized under the laws of Delaware. Carl L. Gordon is a United States citizen. W. Carter Neild is a United States citizen. Geoffrey C. Hsu is a United States citizen. C. Scotland Stevens is a United States citizen. David P. Bonita is a United States citizen. Peter A. Thompson is a United States citizen. Matthew S. Rizzo is a United States citizen. Mona Ashiya is a United States citizen. Trey Block is a United States citizen.

(b) 601 Lexington Avenue, 54th Floor, New York, New York 10022.

(c) OrbiMed Advisors is the managing member or general partner of certain entities as more particularly described in Item 6 below. OrbiMed GP is the general partner of a limited partnership as more particularly described in Item 6 below. OrbiMed Genesis is the general partner of a limited partnership as more particularly described in Item 6 below. Carl L. Gordon is a member of OrbiMed Advisors. W. Carter Neild is a member of OrbiMed Advisors. Geoffrey C. Hsu is a member of OrbiMed Advisors. C. Scotland Stevens is a member of OrbiMed Advisors. David P. Bonita is a member of OrbiMed Advisors. Peter A. Thompson is a member of OrbiMed Advisors. Matthew S. Rizzo is a member of OrbiMed Advisors. Mona Ashiya is a member of OrbiMed Advisors. Trey Block is the Chief Financial Officer of OrbiMed Advisors.

(d) Not applicable.

(e) Not applicable.

(f) Item 2(a) is incorporated herein by reference.

Item 3. Source and Amount of Funds or Other Consideration

In May 2025, OrbiMed Advisors and OrbiMed GP, pursuant to their authority under the limited partnership agreement of OrbiMed Private Investments IX, LP ("OPI IX"), as more particularly described in Item 6 below, caused OPI IX to purchase 4,830,000 shares of common stock, par value $0.0001 per share of the Issuer ("Shares"). In September 2025, OrbiMed Advisors and OrbiMed GP, pursuant to their authority under the limited partnership agreement of OPI IX, caused OPI IX to purchase 40,000,000 shares of Series A preferred stock, par value $0.0001 per share of the Issuer ("Series A preferred stock"). Each outstanding share of Series A preferred stock and common stock converted into Shares at a ratio of 1-for-4.38 immediately upon the completion of the Issuer's initial public offering (the "IPO"). On and prior to the closing of the IPO, OrbiMed Advisors and OrbiMed GP, pursuant to their authority under the limited partnership agreement of OPI IX, caused OPI IX to purchase 1,666,667 Shares in the IPO, and OrbiMed Advisors and OrbiMed Genesis, pursuant to their authority under the limited partnership agreement of OrbiMed Genesis Master Fund, L.P. ("Genesis"), caused Genesis to purchase 273,333 Shares in the IPO, in each case at purchase price of $18.00 per Share. The source of funds for such purchases was the working capital of OPI IX and Genesis.

Item 4. Purpose of Transaction

This Statement on Schedule 13D relates to the acquisition of Shares by the Reporting Persons. The Shares acquired by the Reporting Persons were acquired for the purpose of making an investment in the Issuer and not with the intention of acquiring control of the Issuer's business on behalf of the Reporting Persons' respective advisory clients. The Reporting Persons from time to time intend to review their investment in the Issuer on the basis of various factors, including the Issuer's business, financial condition, results of operations and prospects, general economic and industry conditions, the securities markets in general and those for the Issuer's Shares in particular, as well as other developments and other investment opportunities. Based upon such review, the Reporting Persons will take such actions in the future as the Reporting Persons may deem appropriate in light of the circumstances existing from time to time. If the Reporting Persons believe that further investment in the Issuer is attractive, whether because of the market price of Shares or otherwise, they may acquire Shares or other securities of the Issuer either in the open market or in privately negotiated transactions. Similarly, depending on market and other factors, the Reporting Persons may determine to dispose of some or all of the Shares currently owned by the Reporting Persons or otherwise acquired by the Reporting Persons either in the open market or in privately negotiated transactions. Except as set forth in this Schedule 13D, the Reporting Persons have not formulated any plans or proposals which relate to or would result in: (a) the acquisition by any person of additional securities of the Issuer or the disposition of securities of the Issuer, (b) an extraordinary corporate transaction, such as a merger, reorganization or liquidation, involving the Issuer or any of its subsidiaries, (c) a sale or transfer of a material amount of the assets of the Issuer or any of its subsidiaries, (d) any change in the present Board of Directors or management of the Issuer, including any plans or proposals to change the number or term of directors or to fill any existing vacancies on the board, (e) any material change in the Issuer's capitalization or dividend policy of the Issuer, (f) any other material change in the Issuer's business or corporate structure, (g) any change in the Issuer's charter or bylaws or other instrument corresponding thereto or other action which may impede the acquisition of control of the Issuer by any person, (h) causing a class of the Issuer's securities to be deregistered or delisted from a national securities exchange or to cease to be authorized to be quoted in an inter-dealer quotation system of a registered national securities association, (i) a class of equity securities of the Issuer becoming eligible for termination of registration pursuant to Section 12(g)(4) of the Act or (j) any action similar to any of those enumerated above.

Item 5. Interest in Securities of the Issuer

(a) The following disclosure is based upon 70,652,838 outstanding Shares of the Issuer, as set forth in the Issuer's Form S-1 Amendment filed with the Securities and Exchange Commission (the "SEC") on July 30, 2026. As of the date of this filing, OPI IX, a limited partnership organized under the laws of Delaware, holds 11,901,826 Shares constituting approximately 16.9% of the issued and outstanding Shares. OrbiMed GP is the general partner of OPI IX, pursuant to the terms of the limited partnership agreement of OPI IX, and OrbiMed Advisors is the managing member of OrbiMed GP, pursuant to the terms of the limited liability company agreement of OrbiMed GP. As a result, OrbiMed Advisors and OrbiMed GP share power to direct the vote and disposition of the Shares held by OPI IX and may be deemed directly or indirectly, including by reason of their mutual affiliation, to be the beneficial owners of the Shares held by OPI IX. OrbiMed Advisors exercises this investment and voting power through a management committee comprised of Carl L. Gordon, W. Carter Neild, and Geoffrey C. Hsu, each of whom disclaims beneficial ownership of the Shares held by OPI IX. In addition, OrbiMed Advisors and OrbiMed GP, pursuant to their authority under the limited partnership agreement of OPI IX, caused OPI IX to enter into the agreements referred to in Items 3 and 6. As of the date of this filing, Genesis, a limited partnership organized under the laws of the Cayman Islands, holds 273,333 Shares constituting approximately 0.4% of the issued and outstanding Shares. OrbiMed Genesis is the general partner of Genesis, pursuant to the terms of the limited partnership agreement of Genesis, and OrbiMed Advisors is the managing member of OrbiMed Genesis, pursuant to the terms of the limited liability company agreement of OrbiMed Genesis. As a result, OrbiMed Advisors and OrbiMed Genesis share power to direct the vote and disposition of the Shares held by Genesis and may be deemed, directly or indirectly, including by reason of their mutual affiliation, to be the beneficial owners of the Shares held by Genesis. OrbiMed Advisors exercises this investment and voting power through a management committee comprised of Carl L. Gordon, W. Carter Neild, and Geoffrey C. Hsu, each of whom disclaims beneficial ownership of the Shares held by Genesis. In addition, OrbiMed Advisors and OrbiMed Genesis, pursuant to their authority under the limited partnership agreement of Genesis, caused Genesis to enter into the agreements referred to in Items 3 and 6.

(b) Item 5(a) is incorporated by reference herein.

(c) Except as disclosed in Item 3, the Reporting Persons have not effected any transactions during the past sixty (60) days in any Shares.

(d) Not applicable.

(e) Not applicable.

Item 6. Contracts, Arrangements, Understandings or Relationships With Respect to Securities of the Issuer

In addition to the relationships between the Reporting Persons described in Items 2 and 5 above, OrbiMed GP is the general partner of OPI IX, pursuant to the terms of the limited partnership agreement of OPI IX. Pursuant to this agreement and relationship, OrbiMed GP has discretionary investment management authority with respect to the assets of OPI IX. Such authority includes the power to vote and otherwise dispose of securities held by OPI IX. The number of outstanding Shares of the Issuer attributable to OPI IX is 11,901,826 Shares. OrbiMed GP, pursuant to its authority under the limited partnership agreement of OPI IX, may be considered to hold indirectly 11,901,826 Shares. In addition to the relationships between the Reporting Persons described in Items 2 and 5 above, OrbiMed Genesis is the general partner of Genesis, pursuant to the terms of the limited partnership agreement of Genesis. Pursuant to this agreement and relationship, OrbiMed Genesis has discretionary investment management authority with respect to the assets of Genesis. Such authority includes the power to vote and otherwise dispose of securities held by Genesis. The number of outstanding Shares of the Issuer attributable to Genesis is 273,333 Shares. OrbiMed Genesis, pursuant to its authority under the limited partnership agreement of Genesis, may be considered to hold indirectly 273,333 Shares. In addition to the relationships between the Reporting Persons described in Items 2 and 5 above, OrbiMed Advisors is the managing member of OrbiMed GP and OrbiMed Genesis, pursuant to the terms of the limited liability company agreements of OrbiMed GP and OrbiMed Genesis. Pursuant to these agreements and relationships, OrbiMed Advisors and OrbiMed GP have discretionary investment management authority with respect to the assets of OPI IX. OrbiMed Advisors and OrbiMed Genesis have discretionary investment management authority with respect to the assets of Genesis. Such authority includes the power of OrbiMed GP to vote and otherwise dispose of securities held by OPI IX and the power of OrbiMed Genesis to vote and otherwise dispose of the securities held by Genesis. The number of outstanding Shares attributable to OPI IX is 11,901,826 Shares and the number of Shares attributed to Genesis is 273,333 Shares. Erez Chimovits ("Chimovits"), an employee of OrbiMed Advisors, is a member of the Board of Directors of the Issuer and, accordingly, OrbiMed Advisors and OrbiMed GP may have the ability to affect and influence control of the Issuer. From time to time, Chimovits may receive stock options or other awards of equity-based compensation pursuant to the Issuer's compensation arrangements for non-employee directors. Pursuant to an agreement with OrbiMed Advisors, Chimovits is obligated to transfer any securities issued under any such stock options or other awards, or the economic benefit thereof, to OrbiMed Advisors, which will in turn ensure that such securities or economic benefits are provided to OPI IX. Investors' Rights Agreement In addition, OPI IX and certain other stockholders of the Issuer entered into the Investors' Rights Agreement with the Issuer, dated as of September 3, 2025 (the "Investors' Rights Agreement"). Pursuant to the Investors' Rights Agreement and subject to the terms and conditions therein, the parties agreed that: Form S-1 Registration Rights Upon the completion of the IPO, certain holders of Shares, including those issuable upon the conversion of shares of Series A preferred stock, will be entitled to certain demand registration rights. At any time beginning 180 days after the effective date of the registration statement for the IPO, the holders of a majority of registrable securities then outstanding may request that the Issuer register all or a portion of their Shares on Form S-1 with respect to a majority of the registrable securities then outstanding. With certain exceptions, the Issuer is not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 60 days following the effective date of the registration statement for the IPO. Piggyback Registration Rights After the IPO, in the event that the Issuer proposes to register any of its securities under the Securities Act of 1933, as amended, either for its own account or for the account of other security holders, the holders of such Shares will be entitled to certain piggyback registration rights allowing the holder to include their Shares in such registration, subject to certain marketing and other limitations. Form S-3 Registration Rights Upon the completion of the IPO, certain holders of Shares, including those issuable upon the conversion of shares of Series A preferred stock, will be entitled to certain Form S-3 registration rights. Holders of registrable securities then outstanding can make a request that the Issuer register their Shares on Form S-3 if the Issuer is qualified to file a registration statement on Form S-3 and if the reasonably anticipated aggregate net proceeds of the Shares offered would equal or exceed $5 million. The Issuer will not be required to effect more than two registrations on Form S-3 within any twelve-month period. The right to have such Shares registered on Form S-3 is further subject to other specified conditions and limitations. Expiration of Registration Rights The demand registration rights and short-form registration rights granted under the Investors' Rights Agreement will expire on the earliest to occur of (i) the closing of a deemed liquidation event, as defined in the Issuer's amended and restated certificate of incorporation, (ii) such time after the IPO as the registrable securities held by such holder may be sold within any three-month period without restriction pursuant to Rule 144 or a similar exemption under the Securities Act or (iii) the third anniversary of the IPO. Lock-Up Agreement In addition, in connection with the IPO, OPI IX and Chimovits each entered into a lock-up agreement (the "Lock-Up Agreement") with the Issuer's underwriters pursuant to which, among other things, OPI IX and Chimovits each agreed not to, except in limited circumstances, directly or indirectly, from the date of the Lock-Up Agreement until 180 days after the date of the final prospectus supplement relating to the IPO: (i) offer, sell, contract to sell, pledge, grant any option, right or warrant to purchase, purchase any option or contract to sell, lend or otherwise transfer or dispose of any Shares or any options or warrants to purchase any Shares or any securities convertible into, exchangeable for or that represent the right to receive Shares; (ii) engage in any hedging or other transaction or arrangement (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) which is designed to or which reasonably could be expected to lead to or result in a sale, loan, pledge or other disposition (whether by OPI IX or Chimovits or someone other than OPI IX or Chimovits), or transfer of any of the economic consequences of ownership, in whole or in part, directly or indirectly, of any Shares or any options or warrants to purchase any Shares or any securities convertible into, exchangeable for or that represent the right to receive Shares, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of Shares or other securities, in cash or otherwise; (iii) make any demand for or exercise any right with respect to the registration of any Shares or any securities convertible into, exchangeable for or that represent the right to receive Shares; (iv) otherwise publicly announce any intention to engage in or cause any action, activity, transaction or arrangement described in clause (i), (ii) and (iii) above, as applicable. The foregoing description of the Registration Rights Agreement and the Lockup Agreement do not purport to be complete and are qualified in their entirety by reference to the full texts of the Registration Rights Agreement and the Lock-Up Agreement, which are filed as Exhibit 2 and Exhibit 3, respectively, and incorporated herein by reference.

Item 7. Material to be Filed as Exhibits.

Exhibit Description 1. Joint Filing Agreement among OrbiMed Advisors LLC, OrbiMed Genesis GP LLC, and OrbiMed Capital GP IX LLC. 2. Investors' Rights Agreement, by and between the Issuer and certain of its stockholders, dated as of September 3, 2025 (incorporated by reference to Exhibit 4.2 to the Issuer's Registration Statement on Form S-1, filed with the SEC on July 15, 2026). 3. Form of Lock-Up Agreement (incorporated by reference to Annex II to Exhibit 1.1 to the Issuer's Registration Statement on Form S-1/A, filed with the SEC on July 30, 2026).

SIGNATURE

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

ORBIMED ADVISORS LLC

Signature:	/s/ Carl L. Gordon
Name/Title:	Carl L. Gordon/Member
Date:	08/18/2026

OrbiMed Capital GP IX LLC

Signature:	/s/ Carl L. Gordon
Name/Title:	Carl L. Gordon/Member of OrbiMed Advisors LLC
Date:	08/18/2026

OrbiMed Genesis GP LLC

Signature:	/s/ Carl L. Gordon
Name/Title:	Carl L. Gordon/Member of OrbiMed Advisors LLC
Date:	08/18/2026

Exhibit 1

JOINT FILING AGREEMENT

The undersigned hereby agree that the Statement on Schedule 13D, dated August 7, 2026, with respect to the common stock of Braveheart Bio, Inc. is filed on behalf of each of us pursuant to and in accordance with the provisions of Rule 13d-1(k) under the Securities Exchange Act of 1934, as amended. Each of the undersigned agrees to be responsible for the timely filing of the Statement, and for the completeness and accuracy of the information concerning itself contained therein. This Joint Filing Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the undersigned have executed this Joint Filing Agreement as of the 18th day of August 2026.

ORBIMED ADVISORS LLC

By: /s/ Carl L. Gordon
Name: Carl L. Gordon
Title: Member

ORBIMED CAPITAL GP IX LLC

By: ORBIMED ADVISORS LLC, its managing member

By: /s/ Carl L. Gordon
Name: Carl L. Gordon
Title: Member of OrbiMed Advisors LLC

ORBIMED GENESIS GP LLC

By: ORBIMED ADVISORS LLC, its managing member

By: /s/ Carl L. Gordon
Name: Carl L. Gordon
Title: Member of OrbiMed Advisors LLC