

Loxo Oncology, Inc.
Form SC 13D/A
August 05, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 13D
Under the Securities Exchange Act of 1934
(Amendment No. 2)*

LOXO ONCOLOGY, INC.

(Name of Issuer)

COMMON STOCK

(Title of Class of Securities)

548862101
(CUSIP Number)

OrbiMed Advisors LLC
OrbiMed Capital GP V LLC
Samuel D. Isaly

601 Lexington Avenue, 54th Floor
New York, NY 10022
Telephone: (212) 739-6400

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

August 3, 2016

(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 o.

Note: Schedules filed in paper format shall include a signed original and five copies of the schedule, including all exhibits. See § 240.13d-7(b) for other parties to whom copies are to be sent.

*The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter disclosures provided in a prior cover page.

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. 548862101

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NAME OF REPORTING PERSONS

1

OrbiMed Advisors LLC

CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (See Instructions)

2

(a) ☐

(b) ☐

SEC USE ONLY

3

SOURCE OF FUNDS (See Instructions)

4

N/A

CHECK BOX IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO ITEMS 2(d) or 2(e) ☐

5

CITIZENSHIP OR PLACE OF ORGANIZATION

6

Delaware

SOLE VOTING POWER

7

0

NUMBER OF
SHARES
BENEFICIALLY
OWNED BY
EACH
REPORTING
PERSON

8

SHARED VOTING POWER

2,175,857

SOLE DISPOSITIVE POWER

9

0

SHARED DISPOSITIVE POWER

10

2,175,857

WITH

AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON

11

2,175,857

CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES (See Instructions) ☐

12

PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)

13

10.04%*

TYPE OF REPORTING PERSON (See Instructions)

14

IA

*This percentage is calculated based upon 21,664,333 shares of the Issuer's Common Stock (defined below) outstanding, as set forth in the Issuer's Form 10-Q, dated August 3, 2016 and filed with the SEC (defined below) on August 3, 2016.

SCHEDULE 13D

CUSIP No. 548862101

Page 3 of 12 Pages

NAME OF REPORTING PERSONS

1

OrbiMed Capital GP V LLC

CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (See Instructions)

2

(a) ☐

(b) ☐

SEC USE ONLY

3

SOURCE OF FUNDS (See Instructions)

4

N/A

CHECK BOX IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO ITEMS 2(d) or 2(e) ☐

5

CITIZENSHIP OR PLACE OF ORGANIZATION

6

Delawre

SOLE VOTING POWER

7

NUMBER OF
SHARES

0

BENEFICIALLY

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SOLE DISPOSITIVE POWER

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WITH

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SCHEDULE 13D

CUSIP No. 548862101

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NAME OF REPORTING PERSONS

1

Samuel D. Isaly

CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (See Instructions)

2

(a) ☐

(b) ☐

SEC USE ONLY

3

SOURCE OF FUNDS (See Instructions)

4

N/A

CHECK BOX IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO ITEMS 2(d) or 2(e) ☐

5

CITIZENSHIP OR PLACE OF ORGANIZATION

6

United States

SOLE VOTING POWER

7

0

NUMBER OF
SHARES
BENEFICIALLY
OWNED BY
EACH
REPORTING
PERSON

8

SHARED VOTING POWER

2,175,857

SOLE DISPOSITIVE POWER

9

0

SHARED DISPOSITIVE POWER

10

2,175,857

WITH

AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON

11

2,175,857

CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES (See Instructions) ☐

12

PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)

13

10.04%*

TYPE OF REPORTING PERSON (See Instructions)

14

IN

* This percentage is calculated based upon 21,664,333 shares of the Issuer's Common Stock (defined below) outstanding, as set forth in the Issuer's Form 10-Q, dated August 3, 2016 and filed with the SEC (defined below) on August 3, 2016.

Item 1.

Security and Issuer

This Amendment No. 2 (“Amendment No. 2”) supplements and amends the Statement on Schedule 13D of OrbiMed Advisors LLC, OrbiMed Capital GP V LLC and Samuel D. Isaly originally filed with the Securities and Exchange Commission (the “SEC”) on August 8, 2014 (the “Statement”). The Statement relates to the common stock, par value \$0.0001 per share, of Loxo Oncology, Inc. (the “Common Stock”), a corporation organized under the laws of the state of Delaware (the “Issuer”), with its principal executive offices located at One Landmark Square, Suite 1122, Stamford, CT 06901. The Common Stock is listed on the NASDAQ Global Market under the ticker symbol “LOXO.” Information given in response to each item shall be deemed incorporated by reference in all other items, as applicable.

On May 12, 2016, the Issuer announced the closing of an underwritten public offering of 1,675,000 shares of Common Stock (“Shares”) at \$21.50 per Share, (the “Share Issuance”), including the underwriters’ full exercise of their over-allotment option to purchase up to 251,250 Shares. As a result of the Share Issuance, the Issuer’s total number of outstanding Shares increased to 21,616,960 (the “Outstanding Share Increase”). The Reporting Persons did not participate in, or acquire or dispose of any Shares in the Share Issuance. On August 3, 2016, subsequent to the Share Issuance, the Issuer filed a Form 10-Q with the SEC stating that it had, as of July 31, 2016, 21,664,333 shares of Common Stock outstanding. As a result of the Share Issuance (and more specifically, the Outstanding Share Increase) and the subsequent share increase disclosed on August 3, 2016, the percentage of outstanding Shares that the Reporting Persons may be deemed to beneficially own was reduced by more than one percent of the Issuer’s Shares outstanding.

Item 2.

Identity and Background

(a) This Statement is being filed by OrbiMed Advisors LLC (“Advisors”), a limited liability company organized under the laws of Delaware, OrbiMed Capital GP V LLC (“GP V”), a limited liability company organized under the laws of Delaware, and Samuel D. Isaly (“Isaly”), an individual (collectively, the “Reporting Persons”).

(b) – (c) Advisors, a registered investment adviser under the Investment Advisers Act of 1940, as amended, is the sole managing member of GP V, which is the sole general partner of OrbiMed Private Investments V, LP (“OPI V”), which holds Shares, as more particularly described in Item 3 below. Advisors has its principal offices at 601 Lexington Avenue, 54th Floor, New York, New York 10022.

GP V has its principal offices at 601 Lexington Avenue, 54th Floor, New York, New York 10022.

Isaly, a natural person, is the managing member of Advisors and owns a controlling interest in Advisors.

The directors and executive officers of Advisors and GP V are set forth on Schedules I and II, attached hereto. Schedules I and II set forth the following information with respect to each such person:

- (i) name;
- (ii) business address;
- (iii) present principal occupation or employment and the name, principal business and address of any corporation or other organization in which such employment is conducted; and
- (iv) citizenship.

(d) – (e) During the last five years, neither the Reporting Persons nor any Person named in Schedule I or II have been (i) convicted in a criminal proceeding (excluding traffic violations or similar misdemeanors) or (ii) a party to a civil proceeding of a judicial or administrative body of competent jurisdiction and as a result of such proceeding was or is subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to, federal or state securities laws or finding any violation with respect to such laws.

(f) Isaly is a citizen of the United States.

Item 3. Source and Amount of Funds or Other Consideration

Not applicable. As described more fully in Item 1 above, the event giving rise to the obligation of the Reporting Persons to file this Amendment No. 2 did not involve any transactions effected by one or more Reporting Persons with respect to the Shares.

Item 4. Purpose of Transaction

Not applicable. As described more fully in Item 1 above, the event giving rise to the obligation of the Reporting Persons to file this Amendment No. 2 did not involve any transactions effected by one or more Reporting Persons with respect to the Shares.

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 the Common Stock 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 Statement, 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)-(b) As of the date of this filing, the Reporting Persons may be deemed, for purposes of Rule 13d-3 of the Act, directly or indirectly, including by reason of their mutual affiliation, to be the beneficial owners of the Shares described in Item 3 above. Based upon information contained in the Issuer's Form 10-Q, dated August 3, 2016 and filed with the SEC on August 3, 2016, such Shares constitute approximately 10.04% of the issued and outstanding Shares. Advisors, pursuant to its authority as the sole managing member of GP V, the sole general partner of OPI V, may be deemed to indirectly beneficially own the Shares held by OPI V. GP V, pursuant to its authority as the general partner of OPI V, may be deemed to indirectly beneficially own the Shares held by OPI V. Isaly, pursuant to his authority as the managing member of Advisors and owner of a controlling interest in Advisors, pursuant to its

limited liability company agreement, may also be deemed to indirectly beneficially own the Shares attributable to Advisors. As a result, Isaly, Advisors and GP V share the power to direct the vote and to direct the disposition of the Shares described in Item 3 above.

- (c) The Reporting Persons have not effected any transactions in the shares during the past sixty (60) days.
- (d) Not applicable.
- (e) Not applicable.

Item 6. Contracts, Arrangements, Understandings or Relationship with Respect to Securities of the Issuer

In addition to the relationships between the Reporting Persons described in Items 2, 3 and 5 above, GP V is the sole general partner of OPI V, pursuant to the terms of the limited partnership agreement of OPI V. Advisors is the sole managing member of GP V, pursuant to the terms of the limited liability company agreement of GP V. Pursuant to these agreements and relationships, Advisors and GP V have discretionary investment management authority with respect to the assets of OPI V. Such authority includes the power of GP V to vote and otherwise dispose of securities purchased by OPI V. The number of outstanding Shares attributable to OPI V is 2,175,857 Shares. Advisors and GP V may each be considered to hold indirectly 2,175,857 Shares. Isaly, pursuant to his authority as the managing member of, and owner of a controlling interest in, Advisors, also has shared discretionary power to direct the vote and the disposition of the securities of the Issuer held by OPI V.

David Bonita ("Bonita"), a Private Equity Partner at Advisors, has been a member of the Board of Directors of the Issuer since September 2013, and, accordingly, the Reporting Persons may have the ability to affect and influence control of the Issuer. On June 10, 2016, Bonita was the recipient of a grant of options to purchase 7,812 Shares and currently holds options awarded by the Issuer to purchase an aggregate of 31,249 Shares. From time to time, Bonita may receive additional stock options or other awards of equity-based compensation pursuant to the Issuer's compensation arrangements for non-employee directors. Bonita is obligated to transfer any Shares issued under any such stock options or other awards, or the economic benefit thereof, to the Reporting Persons, which will in turn ensure that such shares or economic benefits are provided to OPI V.

Amended and Restated Investor Rights Agreement

OPI V and certain other stockholders of the Issuer entered into an amended and restated investor rights agreement with the Issuer (the "Investor Rights Agreement"), dated as of July 21 2014. Pursuant to the Investor Rights Agreement and subject to the terms and conditions therein, the parties agreed that:

Demand Registration Rights

The holders of a majority of the shares covered by the Investor Rights Agreement, or their transferees, can, on not more than three occasions, request that the Issuer register all or a portion of their shares. Such request for registration must cover a number of shares with an anticipated aggregate offering price, net of selling expenses, of at least \$10.0 million. The Issuer will not be required to effect a demand registration during the period that is 60 days before the Issuer's good faith estimate of the date of filing of, and ending on a date that is 180 days after the effective date of, a company initiated registration statement relating to an initial public offering of its securities, provided that the Issuer is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective.

Piggyback Registration Rights

The Investor Rights Agreement further provides that, in the event that the Issuer determines 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 stockholders who are party to the Investor Rights Agreement, including OPI V, will be entitled to certain

“piggyback” registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. These rights do not apply with respect to a registration related to employee benefit plans, the offer and sale of debt securities, or corporate reorganizations or certain other transactions.

Form S 3 Registration Rights

The stockholders who are party to the Investor Rights Agreement, including OPI V, will be entitled to make a written request that the Issuer register their shares on Form S 3 (an “S-3 Demand Request”) if the Issuer is eligible to file a registration statement on Form S 3 and if the aggregate price to the public, net of selling expenses, is at least \$750,000. These stockholders may make an unlimited number of S 3 Demand Requests; provided however, the Issuer will not have to effect a registration pursuant to an S-3 Demand Request if the Issuer has effected two (2) registrations pursuant to S-3 Demand Requests within the twelve (12) month period immediately preceding the date of such S-3 Demand Request. The Issuer will also not be required to effect an S-3 Demand Request during the period that is 30 days before the Issuer’s good faith estimate of the date of filing of, and ending on a date that is 90 days after the effective date of, a company initiated registration statement relating to an initial public offering of its securities, provided that the Issuer is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective.

Expenses of Registration

The Issuer will pay the registration expenses of the holders of the shares registered pursuant to the demand, piggyback and Form S 3 registration rights described above.

Indemnification

The Investor Rights Agreement contains customary cross-indemnification provisions, pursuant to which the Issuer is obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to the Issuer, and the selling stockholders are obligated to indemnify the Issuer for material misstatements or omissions attributable to them.

Termination of Registration Rights.

OPI V’s demand, piggyback and Form S 3 registration rights described above generally will terminate upon the earlier of: (i) the date seven years following the Issuer’s initial public offering; (ii) a Deemed Liquidation Event (as defined in the Issuer’s Restated Certificate of Incorporation) or Stock Sale (as defined in the Investor Rights Agreement); or (iii) such time as all of the Registrable Securities (as defined in the Investor Rights Agreement) of the Issuer held by OPI V may be sold without any restriction on volume or manner of sale in any three-month period pursuant to Rule 144.

The foregoing description of the Investor Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Investor Rights Agreement, a copy of which is filed as Exhibit 3 and incorporated herein by reference.

Other than as described in this Schedule 13D, to the best of the Reporting Persons’ knowledge, there are no other contracts, arrangements, understandings or relationships (legal or otherwise) among the persons named in Item 2 and between such persons and any person with respect to any securities of the Issuer.

Item 7.

Materials to Be Filed as Exhibits

Exhibit	Description
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1.	
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Joint Filing Agreement among OrbiMed Advisors LLC, OrbiMed Capital GP V LLC and Samuel D. Isaly

2. Amended and Restated Investors' Rights Agreement by and among the Issuer and each of the persons listed on Schedule A thereto, dated as of July 21, 2014 (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Issuer's Registration Statement on Form S-1 (SEC 333-197123), filed with the SEC on July 21, 2014).
-

SIGNATURE

After reasonable inquiry and to the best of each of the undersigned's knowledge and belief, each of the undersigned certifies that the information set forth in this statement is true, complete and correct.

Dated: August 5, 2016

OrbiMed Advisors LLC

By: /s/ Samuel D. Isaly
Name: Samuel D. Isaly
Title: Managing Member

OrbiMed Capital GP V LLC

By: OrbiMed Advisors LLC
its Managing Member

By: /s/ Samuel D. Isaly
Name: Samuel D. Isaly
Title: Managing Member

Samuel D. Isaly

By: /s/ Samuel D. Isaly
Name: Samuel D. Isaly

Schedule I

The name and present principal occupation of each of the executive officers and directors of OrbiMed Advisors LLC are set forth below. Unless otherwise noted, each of these persons are United States citizens and have as their business address 601 Lexington Avenue, 54th Floor, New York, NY 10022.

Name	Position with Reporting Person	Principal Occupation
Samuel D. Isaly	Managing Member	Managing Member OrbiMed Advisors LLC
Carl L. Gordon	Member	Member OrbiMed Advisors LLC
Sven H. Borho German and Swedish Citizen	Member	Member OrbiMed Advisors LLC
Jonathan T. Silverstein	Member	Member OrbiMed Advisors LLC
W. Carter Neild	Member	Member OrbiMed Advisors LLC
Geoffrey C. Hsu	Member	Member OrbiMed Advisors LLC
Evan D. Sotiriou	Chief Financial Officer	Chief Financial Officer OrbiMed Advisors LLC

Schedule II

The business and operations of OrbiMed Capital GP V LLC are managed by the executive officers and directors of its managing member, OrbiMed Advisors LLC, set forth on Schedule I attached hereto.

EXHIBIT INDEX

Exhibit	Description
1.	Joint Filing Agreement among OrbiMed Advisors LLC, OrbiMed Capital GP V LLC and Samuel D. Isaly
2.	Amended and Restated Investors' Rights Agreement by and among the Issuer and each of the persons listed on Schedule A thereto, dated as of July 21, 2014 (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Issuer's Registration Statement on Form S-1 (SEC 333-197123), filed with the SEC on July 21, 2014).
