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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 8-K

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**Current Report**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

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**Date of Report (Date of earliest event reported): January 5, 2019**

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## ELI LILLY AND COMPANY

(Exact name of registrant as specified in its charter)

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**Indiana**  
(State or Other Jurisdiction  
of Incorporation)

**001-06351**  
(Commission  
File Number)

**35-0470950**  
(I.R.S. Employer  
Identification No.)

**Lilly Corporate Center**  
**Indianapolis, Indiana**  
(Address of Principal Executive Offices)

**46285**  
(Zip Code)

**Registrant's telephone number, including area code: (317) 276-2000**

**No Change**  
(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☒ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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**Item 1.01. Entry into a Material Definitive Agreement**

***Merger Agreement***

On January 5, 2019, Eli Lilly and Company, an Indiana corporation (“Parent”), Bowfin Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of Parent (“Merger Sub”), and Loxo Oncology, Inc., a Delaware corporation (the “Company”) entered into an Agreement and Plan of Merger (the “Merger Agreement”). The Merger Agreement provides that, subject to the terms of the Merger Agreement, Merger Sub will commence a cash tender offer (the “Offer”) to purchase all of the outstanding shares (the “Shares”) of the Company common stock, par value \$0.0001 per share, at a price of \$235.00 per share (the “Offer Price”), net to the seller in cash, without interest, and subject to withholding taxes.

Consummation of the Offer is subject to various conditions set forth in the Merger Agreement, including (i) a majority of shares of the Company common stock then outstanding being tendered in the Offer, (ii) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (iii) the accuracy of the Company’s representations and warranties contained in the Merger Agreement (except, generally, for any inaccuracies that have not had a Company Material Adverse Effect), (iv) the Company’s performance in all material respects of its obligations under the Merger Agreement and (v) the other conditions set forth in Exhibit A to the Merger Agreement. The consummation of the Offer and Merger is not subject to a financing condition.

The Offer will expire at one minute after 11:59 p.m., Eastern time, on the date that is 20 business days following the commencement date of the Offer unless extended in accordance with the terms of the Offer and the Merger Agreement and the applicable rules and regulations of the United States Securities and Exchange Commission (the “SEC”).

Following consummation of the Offer, Merger Sub will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Parent (the “Merger”). In the Merger, each outstanding Share that is not tendered and accepted pursuant to the Offer (other than the Shares held in the treasury of the Company, Shares held by Parent or Merger Sub, and Shares as to which appraisal rights have been perfected in accordance with applicable law) will be cancelled and converted into the right to receive the Offer Price, on the terms and conditions set forth in the Merger Agreement.

The Merger Agreement provides that the Merger will be governed by Section 251(h) of the Delaware General Corporation Law (the “DGCL”) and shall be effected by Merger Sub and the Company as soon as practicable following the consummation of the Offer without a stockholders meeting pursuant to the DGCL.

The Merger Agreement contains customary representations and warranties by Parent, Merger Sub and the Company. The Merger Agreement also contains customary covenants and agreements, including with respect to the operations of the business of the Company between signing and closing, governmental filings and approvals and other matters.

The Merger Agreement contains customary non-solicitation restrictions prohibiting the Company’s solicitation of proposals relating to alternative business combination transactions and restricts the Company’s ability to furnish non-public information to, or participate in any discussions or negotiations with, any third party with respect to any such transaction, subject to customary exceptions in the event of an acquisition proposal that was not solicited in violation of these restrictions and that the Company’s board of directors determines constitutes or could reasonably be expected to lead to a Superior Company Proposal (as defined in the Merger Agreement).

The Merger Agreement contains termination rights for each of Parent, Merger Sub and the Company including by either Parent or the Company if the Offer Closing Time (as defined in the Merger Agreement) shall not have occurred on or before July 5, 2019, or by the Company to enter into an alternative transaction that constitutes a Superior Company Proposal (as defined in the Merger Agreement), and further provides that upon termination of the Merger Agreement under specified circumstances the Company may be required to pay Parent a termination fee of \$265 million.

### ***Tender and Support Agreement***

On January 5, 2019, in connection with the Merger Agreement, Aisling Capital III, LP (“Aisling Capital”) in its capacity as a stockholder of the Company and who beneficially owns approximately 6.6% of the outstanding Shares, entered into a Tender and Support Agreement (the “Tender and Support Agreement”) with Parent and Merger Sub. The Tender and Support Agreement provides, among other things, that Aisling Capital will tender all of the Shares held by it in the Offer.

### **Item 7.01. Regulation FD Disclosure.**

On January 7, 2019, the Company and Parent issued a joint press release regarding the matters described in Item 1.01 of this Current Report on Form 8-K, a copy of which is filed as Exhibit 99.1 and is incorporated herein by reference.

Attached as Exhibit 99.2 and incorporated by reference herein is an investor presentation dated January 2019, that will be used by Parent with respect to the matters described in Item 1.01 of this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibits 99.1 and 99.2, is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liabilities under that section, and shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filings.

### **Item 9.01. Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Joint Press Release issued by Eli Lilly and Company and Loxo Oncology, Inc., dated January 7, 2019.</u></a>
99.2	<a href="#"><u>Investor Presentation of Eli Lilly and Company, dated January 2019.</u></a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**ELI LILLY AND COMPANY**  
(Registrant)

By: /s/ Bronwen L. Mantlo

Name: Bronwen L. Mantlo

Title: Corporate Secretary

Dated: January 7, 2019

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## EXHIBIT INDEX

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99.2	Investor Presentation of Eli Lilly and Company, dated January 2019.



January 7, 2019



Eli Lilly and Company

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Indianapolis, Indiana 46285  
U.S.A.  
+1.317.276.2000  
www.lilly.com

**For Release:**

Immediately

**Refer to:**

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**Lilly Announces Agreement To Acquire Loxo Oncology**

- *Acquisition will broaden the scope of Lilly's oncology portfolio into precision medicines through the addition of a marketed therapy and a pipeline of highly selective potential medicines for patients with genomically defined cancers.*
- *Loxo Oncology's pipeline includes LOXO-292, an oral RET inhibitor being studied across multiple tumor types, which recently was granted Breakthrough Therapy designation by the FDA and could launch in 2020.*
- *Loxo Oncology's Vitrakvi® (larotrectinib) is an oral TRK inhibitor developed and commercialized in collaboration with Bayer that was recently approved by the FDA.*
- *Lilly will commence a tender offer to acquire all outstanding shares of Loxo Oncology for a purchase price of \$235.00 per share in cash, or approximately \$8.0 billion.*
- *Lilly will conduct a conference call with the investment community and media today at 8:45 a.m. EST.*

INDIANAPOLIS, IN and STAMFORD, CT – Eli Lilly and Company (NYSE: LLY) and Loxo Oncology, Inc. (NASDAQ: LOXO) today announced a definitive agreement for Lilly to acquire Loxo Oncology for \$235.00 per share in cash, or approximately \$8.0 billion. Loxo Oncology is a biopharmaceutical company focused on the development and commercialization of highly selective medicines for patients with genomically defined cancers.

The acquisition would be the largest and latest in a series of transactions Lilly has conducted to broaden its cancer treatment efforts with externally sourced opportunities for first-in-class and best-in-class therapies. Loxo Oncology is developing a pipeline of targeted medicines focused on cancers that are uniquely dependent on single gene abnormalities that can be detected by genomic testing. For patients with cancers that harbor these genomic alterations, a targeted medicine could have the potential to treat the cancer with dramatic effect.

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Loxo Oncology has a promising portfolio of approved and investigational medicines, including:

- LOXO-292, a first-in-class oral RET inhibitor that has been granted Breakthrough Therapy designation by the FDA for three indications, with an initial potential launch in 2020. LOXO-292 targets cancers with alterations to the rearranged during transfection (RET) kinase. RET fusions and mutations occur across multiple tumor types, including certain lung and thyroid cancers as well as a subset of other cancers.
- LOXO-305, an oral BTK inhibitor currently in Phase 1/2. LOXO-305 targets cancers with alterations to the Bruton's tyrosine kinase (BTK), and is designed to address acquired resistance to currently available BTK inhibitors. BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas.
- Vitrakvi, a first-in-class oral TRK inhibitor developed and commercialized in collaboration with Bayer that was recently approved by the U.S. Food and Drug Administration (FDA). Vitrakvi is the first treatment that targets a specific genetic abnormality to receive a tumor-agnostic indication at the time of initial FDA approval.
- LOXO-195, a follow-on TRK inhibitor also being studied by Loxo Oncology and Bayer for acquired resistance to TRK inhibition, with a potential launch in 2022.

"Using tailored medicines to target key tumor dependencies offers an increasingly robust approach to cancer treatment," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Laboratories. "Loxo Oncology's portfolio of RET, BTK and TRK inhibitors targeted specifically to patients with mutations or fusions in these genes, in combination with advanced diagnostics that allow us to know exactly which patients may benefit, creates new opportunities to improve the lives of people with advanced cancer."

"We are gratified that Lilly has recognized our contributions to the field of precision medicine and are excited to see our pipeline benefit from the resources and global reach of the Lilly organization," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "Tumor genomic profiling is becoming standard-of-care, and it will be critical to continue innovating against new targets, while anticipating mechanisms of resistance to available therapies, so that patients with advanced cancer have the chance to live longer and better lives."

"Lilly Oncology is committed to developing innovative, breakthrough medicines that will make a meaningful difference for people with cancer and help them live longer, healthier lives," said Anne White, president of Lilly Oncology. "The acquisition of Loxo Oncology represents an exciting and

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immediate opportunity to expand the breadth of our portfolio into precision medicines and target cancers that are caused by specific gene abnormalities. The ability to target tumor dependencies in these populations is a key part of our Lilly Oncology strategy. We look forward to continuing to advance the pioneering scientific innovation begun by Loxo Oncology.”

“We are excited to have reached this agreement with a team that shares our commitment to ensuring that emerging translational science reaches patients in need,” said Jacob Van Naarden, chief operating officer of Loxo Oncology. “We are confident that the work we have started, which includes an FDA approved drug, and a pipeline spanning from Phase 2 to discovery, will continue to thrive in Lilly’s hands.”

Under the terms of the agreement, Lilly will commence a tender offer to acquire all outstanding shares of Loxo Oncology for a purchase price of \$235.00 per share in cash, or approximately \$8.0 billion. The transaction is not subject to any financing condition and is expected to close by the end of the first quarter of 2019, subject to customary closing conditions, including receipt of required regulatory approvals and the tender of a majority of the outstanding shares of Loxo Oncology’s common stock. Following the successful closing of the tender offer, Lilly will acquire any shares of Loxo Oncology that are not tendered into the tender offer through a second-step merger at the tender offer price.

The tender offer represents a premium of approximately 68 percent to Loxo Oncology’s closing stock price on January 4, 2019, the last trading day before the announcement of the transaction. Loxo Oncology’s board recommends that Loxo Oncology’s shareholders tender their shares in the tender offer. Additionally, a Loxo Oncology shareholder, beneficially owning approximately 6.6 percent of Loxo Oncology’s outstanding common stock, has agreed to tender its shares in the tender offer.

This transaction will be reflected in Lilly’s financial results and financial guidance according to Generally Accepted Accounting Principles (GAAP). Lilly will provide an update to its 2019 financial guidance, including the expected impact from the acquisition of Loxo Oncology, as part of its fourth-quarter and full-year 2018 financial results announcement on February 13, 2019.

For Lilly, Deutsche Bank is acting as the exclusive financial advisor and Weil, Gotshal & Manges LLP is acting as legal advisor in this transaction. For Loxo Oncology, Goldman Sachs & Co. LLC is acting as exclusive financial advisor and Fenwick & West LLP is acting as legal advisor.



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### **Conference Call and Webcast**

Lilly will conduct a conference call with the investment community and media today at 8:45 a.m. EST to discuss the acquisition of Loxo Oncology. Investors, media and the general public can access a live webcast of the conference call through the Webcasts & Presentations link that will be posted on Lilly's website at [www.lilly.com](http://www.lilly.com). The webcast of the conference call will be available for replay through February 7, 2019.

### **About LOXO-292**

LOXO-292 is an oral and selective investigational new drug in clinical development for the treatment of patients with cancers that harbor abnormalities in the rearranged during transfection (RET) kinase. RET fusions and mutations occur across multiple tumor types with varying frequency. LOXO-292 was designed to inhibit native RET signaling as well as anticipated acquired resistance mechanisms that could otherwise limit the activity of this therapeutic approach. LOXO-292 has been granted Breakthrough Therapy Designation by the U.S. FDA for three indications, and could launch as early as 2020.

### **About LOXO-305**

LOXO-305 is an investigational, highly selective non-covalent Bruton's tyrosine kinase (BTK) inhibitor. BTK plays a key role in the B-cell antigen receptor signaling pathway, which is required for the development, activation and survival of normal white blood cells, known as B-cells, and malignant B-cells. BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas including chronic lymphocytic leukemia, Waldenstrom's macroglobulinemia, mantle cell lymphoma and marginal zone lymphoma.

### **About Vitrakvi® (larotrectinib)**

Vitrakvi is an oral TRK inhibitor for the treatment of adult and pediatric patients with solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation that are either metastatic or where surgical resection will likely result in severe morbidity, and have no satisfactory alternative treatments or have progressed following treatment. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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### **About LOXO-195**

LOXO-195 is a selective TRK inhibitor that is being investigated to address potential mechanisms of acquired resistance that may emerge in patients receiving Vitrekvi® (larotrectinib) or other multikinase inhibitors with anti-TRK activity.

### **About Eli Lilly and Company**

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [www.lilly.com](http://www.lilly.com) and [www.lilly.com/newsroom/social-channels](http://www.lilly.com/newsroom/social-channels). C-LLY

### **About Loxo Oncology**

Loxo Oncology is a biopharmaceutical company focused on the development and commercialization of highly selective medicines for patients with genomically defined cancers. Our pipeline focuses on cancers that are uniquely dependent on single gene abnormalities, such that a single drug has the potential to treat the cancer with dramatic effect. We believe that the most selective, purpose-built medicines have the highest probability of maximally inhibiting the intended target, with the intention of delivering best-in-class disease control and safety. Our management team seeks out experienced industry partners, world-class scientific advisors and innovative clinical-regulatory approaches to deliver new cancer therapies to patients as quickly and efficiently as possible. For more information, please visit the company's website at <http://www.loxooncology.com>.

### ***Lilly Cautionary Statement Regarding Forward-Looking Statements***

*This press release contains forward-looking statements about the benefits of Lilly's acquisition of Loxo Oncology, Inc. ("Loxo Oncology"). It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in implementing the transaction and in drug development. Among other things, there can be no guarantee that the transaction will be completed in the anticipated timeframe, or at all, or that the conditions required to complete the transaction will be met, that Lilly will realize the expected benefits of the transaction, that the molecules will be approved on the anticipated timeline or at all, or that the potential products will be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission ("the SEC"). Lilly will provide an update to certain elements of its 2019 financial guidance as part of its fourth quarter and full-year 2018 financial results announcement. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.*

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**Loxo Oncology Cautionary Statement Regarding Forward-Looking Statements**

This press release contains “forward-looking statements” relating to the acquisition of Loxo Oncology by Lilly. Such forward-looking statements include the ability of Loxo Oncology and Lilly to complete the transactions contemplated by the merger agreement, including the parties’ ability to satisfy the conditions to the consummation of the offer and the other conditions set forth in the merger agreement and the possibility of any termination of the merger agreement, as well as the role of targeted genomics and diagnostics in oncology treatment and acceleration of our work in developing medicines. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Actual results may differ materially from current expectations because of risks associated with uncertainties as to the timing of the offer and the subsequent merger; uncertainties as to how many of Loxo Oncology’s stockholders will tender their shares in the offer; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the offer or the merger may not be satisfied or waived; the effects of disruption from the transactions contemplated by the merger agreement on Loxo Oncology’s business and the fact that the announcement and pendency of the transactions may make it more difficult to establish or maintain relationships with employees, suppliers and other business partners; the risk that stockholder litigation in connection with the offer or the merger may result in significant costs of defense, indemnification and liability; other uncertainties pertaining to the business of Loxo Oncology, including those set forth in the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of Loxo Oncology’s Annual Report on Form 10-K for the year ended December 31, 2017, which is on file with the SEC and available on the SEC’s website at [www.sec.gov](http://www.sec.gov). Additional factors may be set forth in those sections of Loxo Oncology’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC in the fourth quarter of 2018. In addition to the risks described above and in Loxo Oncology’s other filings with the SEC, other unknown or unpredictable factors could also affect Loxo Oncology’s results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information contained in this press release is provided only as of the date of this report, and Loxo Oncology undertakes no obligation to update any forward-looking statements either contained in or incorporated by reference into this report on account of new information, future events, or otherwise, except as required by law.

**Additional Information about the Acquisition and Where to Find It**

The tender offer for the outstanding shares of Loxo Oncology referenced in this communication has not yet commenced. This announcement is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Loxo Oncology, nor is it a substitute for the tender offer materials that Lilly and its acquisition subsidiary will file with the SEC upon commencement of the tender offer. At the time the tender offer is commenced, Lilly and its acquisition subsidiary will file tender offer materials on Schedule TO, and Loxo Oncology will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. **THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT WILL CONTAIN IMPORTANT INFORMATION. HOLDERS OF SHARES OF LOXO ONCOLOGY ARE URGED TO READ THESE DOCUMENTS CAREFULLY WHEN THEY BECOME AVAILABLE (AS EACH MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME) BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT HOLDERS OF LOXO ONCOLOGY SECURITIES SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SECURITIES.** The Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, will be made available to all holders of shares of Loxo Oncology at no expense to them. The tender offer materials and the Solicitation/Recommendation Statement will be made available for free at the SEC’s web site at [www.sec.gov](http://www.sec.gov).

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*In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, Lilly and Loxo Oncology file annual, quarterly and special reports and other information with the SEC. You may read and copy any reports or other information filed by Lilly or Loxo Oncology at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Lilly's and Loxo Oncology's filings with the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov).*

# # #

# Eli Lilly and Company

## Acquisition of Loxo Oncology

January 7, 2019

*Lilly*

# Agenda

## **Transaction Highlights and Strategic Rationale**

Dave Ricks, Chairman and Chief Executive Officer

## **Combination with Lilly Oncology**

Anne White, President, Lilly Oncology

## **Loxo Oncology Portfolio Overview**

Dan Skovronsky, M.D., Ph.D., Chief Scientific Officer  
and President, Lilly Research Labs

## **Financial Implications**

Josh Smiley, Chief Financial Officer

## **Question and Answer Session**

## SAFE HARBOR PROVISION



During this conference call, we anticipate making projections and forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. For example, our results – alone or following the completion of this acquisition – may be affected by competitive developments; the timing and success of new product launches; regulatory and legal matters; patent disputes; government investigations; governmental actions regarding pricing, importation and reimbursement; changes in tax law; acquisitions; business development transactions; the state of the financial markets; and the impact of exchange rates.

Also, the proposed acquisition is subject to customary closing conditions, including a successful tender offer and antitrust clearance. For additional information about relevant risk factors, please refer to both Lilly's and Loxo Oncology's Forms 10-K and 10-Q.

Finally, the information we provide about our products and pipeline is for the benefit of the investment community. It is not intended to be promotional and is not sufficient for prescribing decisions.

The company undertakes no duty to update forward-looking statements.

## ADDITIONAL INFORMATION ABOUT THE ACQUISITION AND WHERE TO FIND IT



The tender offer for the outstanding shares of Loxo Oncology referenced in this communication has not yet commenced. This communication is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Loxo Oncology, nor is it a substitute for the tender offer materials that Lilly and its acquisition subsidiary will file with the SEC upon commencement of the tender offer. At the time the tender offer is commenced, Lilly and its acquisition subsidiary will file tender offer materials on Schedule TO, and Loxo Oncology will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT WILL CONTAIN IMPORTANT INFORMATION. HOLDERS OF SHARES OF LOXO ONCOLOGY ARE URGED TO READ THESE DOCUMENTS CAREFULLY WHEN THEY BECOME AVAILABLE (AS EACH MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME) BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT HOLDERS OF LOXO ONCOLOGY SECURITIES SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SECURITIES. The Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, will be made available to all holders of shares of Loxo Oncology at no expense to them. The tender offer materials and the Solicitation/Recommendation Statement will be made available for free at the SEC's web site at [www.sec.gov](http://www.sec.gov).

In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, Lilly and Loxo Oncology file annual, quarterly and current reports and other information with the SEC. Lilly's and Loxo Oncology's filings with the SEC are available for free to the public from commercial document-retrieval services and at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov).



# STRATEGIC RATIONALE

Loxo Oncology acquisition consistent with Lilly strategy



## Grow Revenue



- Brings opportunity for multiple near-term launches, bolstering oncology franchise
- Enhances growth prospects post-Alimta patent expiration
- Contributes revenue in 2019

## Improve Productivity



- No changes to 2020 operating margin goal
- Targeted oncology is an efficient operating model
- Deal accretive to operating margins over time

## Create Long-Term Value



- Consistent with strategy to upgrade pipeline and enhance future growth through business development
- Potential for meaningful value contribution well into 2030s

## Speed Life-Changing Medicines



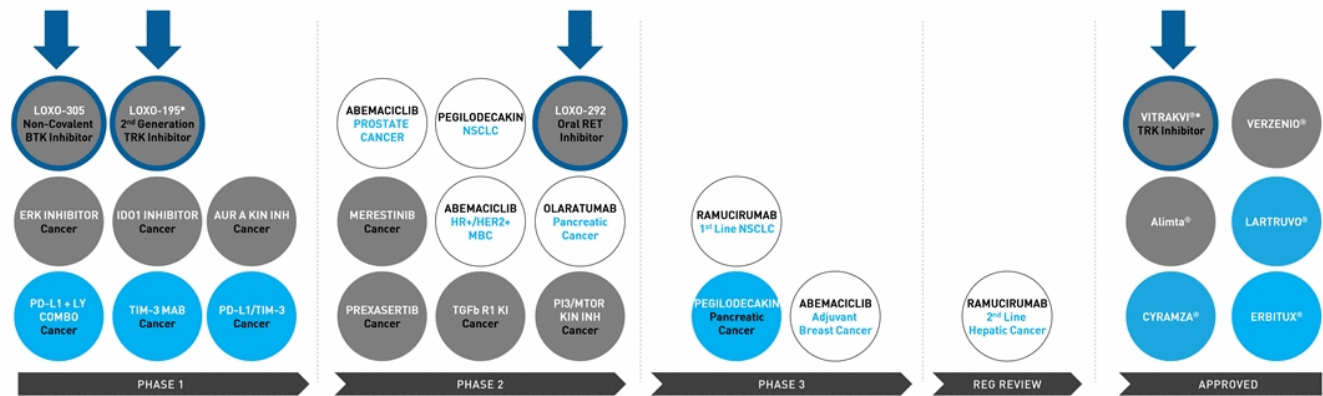
- Therapies with significant effect size in targeted populations
- Potential to launch multiple first-and/or best-in-class medicines
- Multiple assets de-risked clinically

# LILLY ONCOLOGY PORTFOLIO ENHANCED

Existing Lilly Oncology Pipeline as of January 4, 2019



- LEGEND**
- CHEMICAL ENTITY
  - BIOTECH ENTITY
  - NILEX
  - LOXO Additions
  - Commercial Collaboration



Not for promotional use

# LOXO ONCOLOGY PORTFOLIO

Highly selective, targeted cancer therapies for specific tumor mutations



PRECLINICAL	EARLY STAGE DEVELOPMENT	LATE STAGE DEVELOPMENT	REGULATORY SUBMISSION	APPROVED
VITRAKVI® (larotrectinib) – TRK Inhibitor, in collaboration with Bayer				
			EU	U.S.
LOX0-292 – Cancers harboring RET-fusions or activating RET-mutations				
LOX0-195 – Second generation TRK inhibitor for potential acquired resistance, in collaboration with Bayer				
LOX0-305 – Non-covalent BTK inhibitor for B-cell malignancies and potential acquired resistance				
Second generation RET inhibitors for potential acquired resistance				
FGFR Program – Cancers harboring alterations of fibroblast growth factor receptor (FGFR)				

# VITRAKVI (LAROTRECTINIB)

SELECTIVE ORAL TRK INHIBITOR IN COLLABORATION WITH BAYER<sup>[1]</sup>



## KEY ATTRIBUTES

### First in class

- FDA accelerated approval November 2018
- Submitted to EMA in August 2018

### Best in class

- 75% overall response rate (ORR) across various solid tumors in adults and children<sup>[2]</sup>
  - 53% partial response<sup>[2]</sup>
  - 22% complete response<sup>[2]</sup>
- First treatment with tumor-agnostic indication at time of initial FDA approval

### Observed adverse events mostly grade 1/2

## DATA PRESENTATIONS

### NEJM publication February 2018

- Clinical data in 55 patients with TRK fusion cancer

### ITPCC September 2018

- Poster with clinical data in children and adolescents with TRK fusion metastatic thyroid carcinoma

### IASLC World Lung September 2018

- Presentation of clinical data in TRK fusion NSCLC

### American Thyroid Association October 2018

- Poster of clinical data in TRK fusion thyroid cancer

### ESMO October 2018

- Presentation of one year follow-up data for 55 patients in NEJM, and additional 67 enrolled subsequently

Abbreviations: NEJM=New England Journal of Medicine; ITPCC=Integrative Therapies Program for Children with Cancer; IASLC=International Association for the Study of Lung Cancer; ESMO=European Society for Medical Oncology

[1] Loxo Oncology leads global development activities and U.S. regulatory activities. Bayer leads ex-U.S. regulatory activities and worldwide commercial activities. Globally, Bayer and Loxo Oncology share development costs 50/50. In the U.S., there is co-promotion agreement. Globally, Bayer books sales. Loxo Oncology receives 50% of U.S. operating profit and a royalty outside the U.S.

[2] Per U.S. Prescribing Information.

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# LOXO-195

NEXT GENERATION TRK INHIBITOR IN COLLABORATION WITH BAYER<sup>(1)</sup>



## KEY ATTRIBUTES

### Continuation of TRK franchise

- Designed to address acquired resistance in patients treated with TRK inhibitors

### Currently being evaluated in Phase 1 / 2 study

- Study initiated in July 2017
- Granted Orphan Drug Designation by FDA
- Phase 1 data expected 1H 2019

### Projected submission in 2021, potential regulatory action in 2022

## DATA PRESENTATIONS

### AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2016

- Data presented on potency, specificity and favorable in-vivo properties in animals

### Cancer Discovery June 2017

- Research brief outlining preclinical rationale

Abbreviations: AACR=American Association for Cancer Research; NCI=National Cancer Institute; EORTC=European Organization for Research and Treatment of Cancer

(1) Loxo Oncology leads global development activities and U.S. regulatory activities. Bayer leads ex-U.S. regulatory activities and worldwide commercial activities. Globally, Bayer and Loxo Oncology share development costs 50/50. In the U.S., there is co-promotion agreement. Globally, Bayer books sales. Loxo Oncology receives 50% of U.S. operating profit and a royalty outside the U.S.

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# LOXO-292

HIGHLY SELECTIVE ORAL RET INHIBITOR, FULLY OWNED BY LOXO ONCOLOGY



## KEY ATTRIBUTES

### Potentially first-in-class, launching in 2020

- Breakthrough Therapy designation for three indications:
  - RET-fusion positive NSCLC, RET-fusion positive thyroid cancer and RET-mutant medullary thyroid cancer
- Currently in Phase 2 portion of LIBRETTO-001 study
- Pending regulatory discussions, potential for U.S. submission in late 2019

### Potentially best in class

- ORR rates: RET-fusion positive NSCLC (68%)<sup>[1]</sup>, RET-fusion positive thyroid cancer (78%)<sup>[2]</sup> and RET-mutant medullary thyroid cancer (59%)<sup>[2]</sup>
- Presentation of registrational Phase 2 data 2H 2019

### Adverse events mostly grade 1/2

## DATA PRESENTATIONS

### ASCO June 2018

- 82 patients with RET-altered cancers

### IASLC World Lung September 2018

- Update from ASCO in 38 patients with RET fusion positive NSCLC

### American Thyroid Association October 2018

- Update from ASCO in 38 patients with RET-mutant medullary thyroid cancer and RET fusion-positive thyroid cancer

Abbreviations: ASCO=American Society of Clinical Oncology; IASLC – International Association for the Study of Lung Cancer  
Not for promotional use

[1] Data presented at IASLC World Lung 2018  
[2] Data presented at American Thyroid Association 2018

# LOXO-305

HIGHLY SELECTIVE NON-COVALENT BTK INHIBITOR, FULLY OWNED BY LOXO ONCOLOGY



## KEY ATTRIBUTES

Designed to address resistance and intolerance in patients treated with approved BTK inhibitors

- BTK is a validated therapeutic target in numerous B-cell malignancies
- LOXO-305 is highly active against wild-type BTK and cysteine-481 mutated BTK, which frequently drives resistance to covalent BTK inhibitors

Phase 1 / 2 trial initiated December 2018

- Patients with various B-cell leukemias and lymphomas

## DATA PRESENTATIONS

Society of Hematologic Oncology Annual Meeting September 2018

- Preclinical characterization data

# FINANCIAL IMPLICATIONS

## OFFER SUMMARY AND SOURCES OF VALUE



### OFFER SUMMARY

All-cash tender at \$235.00 per share

Premium of approximately 68% to the closing share price on January 4, 2019

Aggregate purchase price of approximately \$8.0 billion

Net of Loxo Oncology cash and investments, purchase price of approximately \$7.2B



### SOURCES OF VALUE

Several sources of value across Loxo Oncology pipeline, with multiple assets de-risked clinically

LOXO-292 most substantial single component

Significant value from TRK franchise

LOXO-305 ascribed modest value given early stage of development

Potential upside from pre-clinical pipeline





# FINANCIAL IMPLICATIONS

## FINANCING SUMMARY AND FINANCIAL IMPACT



### FINANCING SUMMARY

Combination of cash and debt to fund acquisition

Maintain flexibility to pursue licensing and M&A within current credit rating

No change to dividend policy

Likely limit share repurchases to \$3.5 billion during 1H 2019



### FINANCIAL IMPACT

No changes to 2020 financial expectations

Impact to 2019 Financial Guidance to be updated in Q4 2018 earnings announcement in February 2019

Potentially accretive on cash basis in 2022

Potential to drive significant revenue and margin expansion over time



# Summary

Loxo Oncology is an exciting acquisition for Lilly, continuing our strategy of utilizing external innovation to augment internal research and development efforts

Targeted therapies and genetic-based diagnostics offer significant potential to improve the lives of people with advanced cancer

Loxo Oncology's portfolio has potential to contribute multiple first-in-class and/or best-in-class therapies

Transaction bolsters Lilly's oncology franchise and has potential to drive significant growth in the mid-term

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Grow Revenue

Improve Productivity

Speed Life-Changing  
Medicines

Create Long-Term Value

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## **Question and Answer Session**