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

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# SCHEDULE TO

**Tender Offer Statement under Section 14(d)(1) or 13(e)(1)**
**of the Securities Exchange Act of 1934**

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# Loxo Oncology, Inc.
**(Name of Subject Company (Issuer))**

**Bowfin Acquisition Corporation**
**a wholly owned subsidiary of**

**Eli Lilly and Company**
**(Names of Filing Persons (Offerors))**

**Common Stock, $0.0001 par value per share**
**(Title of Class of Securities)**

**548862101**
**(CUSIP Number of Class of Securities)**

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**CALCULATION OF FILING FEE**

| Transaction Valuation | Amount of Filing Fee* |
|---|---|
| N/A* | N/A* |

* Pursuant to General Instruction D to Schedule TO, a filing fee is not required in connection with this filing because it relates solely to preliminary communications made before the commencement of a tender offer.

☐ Check the box if any part of the fee is offset as provided by Rule 0-11(a)(2) and identify the filing with which the offsetting fee was previously paid. Identify the previous filing by registration statement number, or the form or schedule and the date of its filing.

Amount Previously Paid: N/A
Form of Registration No.: N/A
Filing Party: N/A
Date Filed: N/A

☒ Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.

Check the appropriate boxes below to designate any transactions to which the statement relates:

☒ Third-party tender offer subject to Rule 14d-1.
☐ Issuer tender offer subject to Rule 13e-4.
☐ Going-private transaction subject to Rule 13e-3.

☐ Amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer: ☐

If applicable, check the appropriate box(es) below to designate the appropriate rule provision(s) relied upon:

☐ Rule 13e-4(i) (Cross-Border Issuer Tender Offer)
☐ Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

This Tender Offer Statement on Schedule TO (this "Statement") relates solely to preliminary communications made before the commencement of a planned tender offer by Bowfin Acquisition Corporation ("Purchaser"), a wholly-owned subsidiary of Eli Lilly and Company ("Lilly"), for all of the outstanding shares of common stock of Loxo Oncology, Inc. (the "Company"), to be commenced pursuant to the Agreement and Plan of Merger, dated as of January 5, 2019, among Lilly, Purchaser and the Company.

In connection with the proposed acquisition, Lilly will cause Purchaser to commence a tender offer for the outstanding shares of the Company. The tender offer has not yet commenced. This document is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of the Company, nor is it a substitute for the tender offer materials that Lilly and its acquisition subsidiary, Purchaser, will file with the SEC upon commencement of the tender offer. At the time the tender offer is commenced, Lilly and Purchaser will file tender offer materials on Schedule TO, and the Company will file a Solicitation/Recommendation Statement on Schedule 14D-9 (the "Solicitation/Recommendation Statement") 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 the Company are urged to read these documents when they become available because they will contain important information that holders of shares of the Company should consider before making any decision regarding tendering their shares. 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 the Company 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.

**EXHIBIT INDEX**

| | |
|---|---|
| Exhibit 99.1 | Transcript of Investor Relations Call of January 7, 2019. |

**C O R P O R A T E  P A R T I C I P A N T S**

**Anne E. White** *Eli Lilly and Company - Senior VP & President of Lilly Oncology*

**Daniel M. Skovronsky** *Eli Lilly and Company - Senior VP for Science & Technology & President of Lilly Research Labs*

**David A. Ricks** *Eli Lilly and Company - Chairman, CEO & President*

**Joshua L. Smiley** *Eli Lilly and Company - Senior VP & CFO*

**Kevin Hern**

**Levi Garraway** *Eli Lilly and Company - SVP of Global Development & Medical Affairs - Oncology Business*

**C O N F E R E N C E  C A L L  P A R T I C I P A N T S**

**David Reed Risinger** *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

**Geoffrey Christopher Meacham** *Barclays Bank PLC, Research Division - MD & Senior Research Analyst*

**John Thomas Boris** *SunTrust Robinson Humphrey, Inc., Research Division - MD*

**Louise Alesandra Chen** *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

**Seamus Christopher Fernandez** *Guggenheim Securities, LLC, Research Division - Senior Analyst of Global Pharmaceuticals*

**Stephen Michael Scala** *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

**Umer Raffat** *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

**Vamil Kishore Divan** *Crédit Suisse AG, Research Division - Senior Analyst*

**P R E S E N T A T I O N**

**Operator**

Ladies and gentlemen, thank you for standing by, and welcome to the Eli Lilly acquisition of Loxo Oncology (Operator Instructions) As a reminder, this conference is being recorded.

I'd now like to turn the conference over to Kevin Hern. Please go ahead.

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**Kevin Hern**

Thank you, Linda. Good morning. Thank you for joining us on this conference call to discuss Eli Lilly and Company's proposed acquisition of Loxo Oncology. I'm Kevin Hern, Vice President of Investor Relations. Joining me on today's call are Dave Ricks, our Chairman and Chief Executive Officer; Josh Smiley, Chief Financial Officer; Dr. Dan Skovronsky, President of Lilly Research Laboratories; Anne White, President of Lilly Oncology; and Dr. Levi Garraway, Senior Vice President of Oncology R&D.

You can access the press release and supporting materials regarding today's announcement, as well as a replay of this call, at lilly.com.

During this conference call, we anticipate making projections and forward-looking statements based on our current expectations. Our actual results alone or following the completion of this acquisition could differ materially due to a number of factors, including those listed on Slide 3 and those outlined in Lilly's and Loxo Oncology's latest forms 10-K and 10-Q filed with the Securities and Exchange Commission.

The tender offer for the outstanding shares of Loxo Oncology referenced today has not yet commenced. This conference call is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Loxo Oncology. Please refer to the information on Slide 4 for more details about the upcoming tender offer.

Also, the proposed acquisition is subject to customary closing conditions, including a successful tender offer and antitrust clearance. 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.

I will now turn the call over to Dave.

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**David A. Ricks** - *Eli Lilly and Company - Chairman, CEO & President*

Thanks, Kevin. We're excited to announce that Lilly has signed an agreement to acquire Loxo Oncology for $235 per share or approximately $8 billion. This acquisition brings multiple new medicines into the Lilly portfolio and expands our presence — our oncology presence into precision medicines.

As shown on Slide 5, this acquisition squarely aligns with our stated strategy. It provides the opportunity to launch multiple first-in-class and best-in-class therapies, drive revenue growth, continue our margin expansion and create long-term value for Lilly's shareholders. Importantly, it offers the potential to deliver breakthrough innovation to patients, raising the level of care for people with cancer.

As we shared at our investor update on December 19, replenishing Lilly's pipeline is a key focus during the next several years, both from our own labs and through external innovation. In 2018, we added 3 high-value assets to our late-phase pipeline: mirikizumab, tirzepatide and pegilodecakin, each with an opportunity to be first or best in its class. The acquisition of Loxo Oncology and specifically LOXO-292 further upgrades our late-stage pipeline, continuing this trend.

As we have said in the past, oncology is an area where we are committed to improving our competitive position. This transaction, the largest and most recent in a series of oncology deals, helps increase the number of opportunities in our pipeline to deliver first-in-class and best-in-class cancer therapies to improve outcomes for patients.

I'll now turn the call over to Anne to provide an overview of Loxo Oncology's portfolio and its fit within Lilly Oncology. Anne?

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**Anne E. White** - *Eli Lilly and Company - Senior VP & President of Lilly Oncology*

Well, thank you, Dave, and moving to Slide 6. We are very excited about the further expansion of Lilly's oncology portfolio into medicines that target cancers caused by gene abnormalities. The acquisition of Loxo Oncology is another example of leveraging business development to bring first-in-class or best-in-class medicines to patients. This transaction provides Lilly with the potential to have 3 additional near- to midterm launches in oncology.

Combined with our previously executed acquisitions of ARMO BioSciences and AurKa, we have augmented our internal portfolio with multiple assets that meet our high bar for development.

Moving on to Slide 7, you'll see an overview of Loxo Oncology's portfolio. Loxo has built a pipeline of personalized cancer therapies for specific mutations across multiple tumor types that have the potential to provide robust single-agent tumor control while limiting off-target side effects.

Loxo Oncology's pipeline includes Vitrakvi, which is a first-in-class TRK inhibitor in collaboration with Bayer that was recently granted accelerated approval by the FDA in November of 2018, and it's also been submitted in Europe. This first approval serves as validation of Loxo Oncology's approach of targeting genetically defined tumors.

LOXO-292, which is a wholly owned first-in-class oral RET inhibitor, is currently in the Phase II portion of a Phase I/II study across multiple tumor types. It's been granted breakthrough therapy designation by the FDA for 3 indications.

LOXO-195, which is a follow-on TRK inhibitor to Vitrakvi, has an ongoing Phase I/II study for acquired resistance to TRK inhibition. LOXO-195 is also part of the collaboration with Bayer.

LOXO-305, which is a BTK inhibitor currently in a Phase I/II study, targets cancers of alterations to the Bruton's tyrosine kinase, or BTK, and is designed to address acquired resistance to currently available BTK inhibitors. And 2 preclinical programs pursuing second-generation RET inhibitors for potential acquired resistance and cancers harboring alterations of the fibroblast growth factor receptor, FGFR.

So I'll now, with pleasure, turn the call over to Dan to talk about each asset in more detail.

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**Daniel M. Skovronsky** - *Eli Lilly and Company - Senior VP for Science & Technology & President of Lilly Research Labs*

Thanks, Anne. Slide 8 provides an overview of Vitrakvi, the first ever TRK inhibitor and the first treatment to receive a tumor agnostic indication at the time of initial FDA approval.

In clinical trials of patients with TRK fusion cancer across various tumor types, Vitrakvi demonstrated compelling efficacy as reflected in the U.S. label, including an overall response rate of 75% with 22% of patients achieving complete response.

In addition, follow-up data from the first cohort and data from new patient exposures was presented at ESMO in October 2018. These data were consistent with data that supported submission, demonstrating nearly identical response rates. We are also encouraged by the durability of response observed in clinical trials. As of a July 2018 data cutoff, median duration of response had not yet been reached after approximately 18 months of follow-up.

Finally, the tolerability profile of Vitrakvi remains encouraging and consistent across data presentations, with most diverse events reported as grade I or II, further supporting the long duration of therapy.

We look forward to the benefit Vitrakvi will bring to patients across a variety of tumor types. It's estimated that TRK fusions are present in 0.2% of all solid tumors.

Turning to Slide 9. LOXO-195 is a next-generation TRK inhibitor, currently in Phase I development, designed to address certain mechanisms of acquired resistance in patients who've stopped responding to TRK inhibitors. Despite durable responses to TRK-directed therapy, it's expected that acquired resistance to therapy may ultimately emerge for many patients.

LOXO-195 could address resistance in these patients, effectively extending the duration of therapy for the TRK franchise.

The Phase I/II study was initiated in July of '17 and was granted orphan drug designation by the FDA in October 2018. Phase I data is expected in the first half of this year, and we also hope to share data from the program at a medical meeting.

Moving on to Slide 10. LOXO-292 is a wholly owned, potentially first-in-class, highly selective oral RET inhibitor for the treatment of patients with cancers that harbor RET fusions or activating RET mutations. These genomic alterations in the RET kinase lead to overactive RET signaling and uncontrolled cell growth.

RET is a rare driver of multiple diverse tumor types and RET fusions are estimated to be present in 2% to 3% of non-small cell lung cancer, 10% to 20% of papillary thyroid cancers and a subset of other cancers.

Activating RET point mutations are estimated to be present in 60% of medullary thyroid cancer.

LOXO-292 is currently in a Phase II portion of a global Phase I/II study and has received 3 breakthrough therapy designations from the FDA in RET fusion positive non-small cell lung cancer, RET fusion positive thyroid cancer and RET mutant medullary thyroid cancer.

Current plans are to present registrational Phase II data for the program in the second half of 2019, ahead of a potential U.S. filing in late 2019, pending regulatory discussions. This could lead to a regulatory action and launch in 2020, offering patients and their doctors the first selective RET inhibitor.

LOXO-292 has demonstrated early evidence of robust efficacy and durable activity in RET mutated patients and non-small cell lung cancer and thyroid cancer.

Data presented at IASLC World Lung in September 2018 for non-small cell lung cancer showed an overall response rate of 68%, 26 of 38 patients, for RET fusion positive patients, with 96% of responding patients remaining on therapy as the cutoff date.

At the 2018 American Thyroid Association Conference in October 2018, data presented showed an overall response rate of 59%, 17 of 29 patients, in RET mutant medullary thyroid cancer and 78%, 7 of 9 patients, in RET fusion positive thyroid cancer.

In addition, the percentage of responders remaining on therapy as of the cutoff date was remarkably high at 94% and 100%, respectively.

Across tumor types, multiple patients have remained on treatment for over 1 year with responses ongoing.

Added to the current tolerability profile, where most treatment emergent adverse events were grade I or II in severity, this indicates the potential for lengthy treatment duration for LOXO-292.

We believe LOXO-292 is a first-in-class RET inhibitor with a compelling efficacy and durability profile, has the potential to provide significant benefit to patients across multiple tumor types and drive meaningful, long-term value for Lilly.

On Slide 11, LOXO-305 is a highly selective, next-generation, non-covalent BTK inhibitor for overcoming acquired resistance to covalent BTK inhibitors. BTK is a validated molecular target found across numerous B-cell malignancies and many BTK inhibitors that are approved or in late-stage development have the same binding mode and therefore, all cause the same progression events described in patients.

LOXO-305 was specifically designed to address this mechanism of acquired resistance and intolerance in patients treated with approved BTK inhibitors.

In addition to targeting wild-type BTK, it's highly active against cysteine 481 mutated BTK, which frequently drives resistance to covalent BTK inhibitors.

Presently, tens of thousands of patients are undergoing chronic therapy with BTK inhibitors. Though the exact number of patients who develop a C481 resistance mutation is not known, we believe it may be responsible for a meaningful component of disease progression cases on covalent BTK inhibitors.

As more patients go on covalent BTK inhibitor therapies for longer periods of times, the addressable population is expected to increase, creating an unmet medical need which could result in a significant market opportunity.

The Phase I/II study of LOXO-305 was initiated December 2018 and will be enrolling patients in various B cell leukemias and lymphomas.

I'll now turn the call over to Josh to discuss financial implications.

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**Joshua L. Smiley** - *Eli Lilly and Company - Senior VP & CFO*

Thanks, Dan. Slide 12 provides a summary of the offer and sources of value for the transaction. The agreement is an all-cash tender offer at $235 per share for an aggregate purchase price of approximately $8 billion, which represents a premium of approximately 68% to the closing share price on January 4, 2019.

Net of Loxo Oncology's cash and investments, this results in a net purchase price of approximately $7.2 billion.

While there are several sources of value for this acquisition with multiple assets de-risked clinically, LOXO-292 is the most substantial single-value component in the transaction.

We also see significant and near-term value from the 2 assets in the TRK franchise. And although LOXO-305 is early in development, it could address a significant unmet need, if clinically successful.

Moving to Slide 13. Lilly will use a combination of cash and debt to fund the acquisition, while retaining financial flexibility to pursue licensing and M&A within our current credit rating.

We will have no change to our dividend policy. However, this transaction is likely to limit our share repurchases this year to $3.5 billion during the first half of 2019.

While this transaction will put modest downward pressure on margins in the near term, our goal is still to achieve 2020 operating income as a percent of sales of 31%. And in the mid to long term, we see this transaction as being accretive to margins.

Additionally, this acquisition has the potential to be accretive on a cash basis by 2022, with the potential to add substantial revenue and operating profit over time.

The impact to 2019 financial guidance will be updated in Lilly's Q4 2018 earnings announcement in February.

Now back to Dave for a short summary before we move to the Q&A.

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**David A. Ricks** - *Eli Lilly and Company - Chairman, CEO & President*

Thanks, Josh. Finally, on Slide 14, the Loxo Oncology acquisition is an exciting opportunity to expand our oncology portfolio.

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

This acquisition has the potential to contribute multiple first-in-class and/or best-in-class medicines to our portfolio and in patients with cancer, bolstering our oncology franchise and driving future revenue growth and margin expansion, ultimately creating value for Lilly's shareholders.

This concludes our prepared remarks. Now I'll turn the call over to Kevin to moderate the Q&A session.

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**Kevin Hern**

Thanks, Dave. (Operator Instructions) Linda, please provide the instructions for the Q&A session and then we're ready for the first caller.

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**Q U E S T I O N S A N D A N S W E R S**

**Operator**

(Operator Instructions) And our first name goes to the — first question goes to the line of Steve Scala.

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**Stephen Michael Scala** - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Congratulations on the transaction. I have 2 questions. First, what is Lilly assuming for duration of use of LOXO-292? And the second question is that Lilly 2019 EPS guidance was last stated at $5.90 to $6. I appreciate that Lilly will be updating 2019 guidance in February, but back of the envelope suggests a new range will be about $5.40 to $5.50. Any comments on that?

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**Kevin Hern**

Thanks, Steve. We'll go to Levi for the first question and then Josh on guidance.

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**Levi Garraway** - *Eli Lilly and Company - SVP of Global Development & Medical Affairs - Oncology Business*

Yes. Thanks, Steve, for the question. So as Dan mentioned in his opening comments, LOXO-292 has not only high response rates in lung cancer and the various types of thyroid cancer, but it's also the case that anywhere from 94% to 100% of patients, depending on the incidence, are still on therapy at the time of cutoff. So obviously, we don't have exact data to model median time on therapy, but certainly, these data are encouraging and suggest that patients who benefit from this medicine may receive benefit for a robust period of time, so we obviously take it into the specifics of what that modeling looks like, but certainly, the data are very encouraging for duration of response.

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**Joshua L. Smiley** - *Eli Lilly and Company - Senior VP & CFO*

Steve, it's Josh on your question about guidance for 2019 and impacts. First, the reason we're not providing guidance now is because we're still working through the final accounting for the transaction, whether we account for it as an asset acquisition or business combination, so we'll work through those details and that'll have some impact on both GAAP and non-GAAP EPS. But at a high level, I'd say a couple of things. The guidance that we provided in December for 2019, we had already contemplated some use of cash for an acquisition. We planned for about $3.5 billion. So there certainly will be incremental OID financing cost here, but it's not the full purchase price. And then from an operating income perspective, what we'll see here is the biggest impact will be R&D expense to continue to progress the portfolio. But I'd say, at a high level, your estimates are probably a little bit high in terms of the amount of impact relative to our current non-GAAP guidance, but that will be updated in February.

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**Kevin Hern**

Thanks, Josh.

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**Operator**

(Operator Instructions) And next, we'll go to the line of Umer Raffat.

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**Umer Raffat** - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

I wanted to touch upon a couple of things very quickly. Number one, can you give us a sense for the valuation of TRK versus RET versus BTK? And I ask because Bayer seems to have put a valuation out for the TRK franchise effectively, right, about $3 billion based on the — about $3 billion, which is $1.5 billion from there and to the milestone. So I just wanted to understand if RET was by far the most important part of the valuation that you're paying for, one. And also, on the same lines on the TRK, I was curious. What's the number of identified patients with a TRK fusion that you've identified? And I ask because Loxo had a very wide range out there for that. I think that will be really helpful for Lilly models as well as for people that are tracking the launch as a proxy for how good a deal this was, et cetera. And just to wrap it up, I noticed the composition plan on their TRK to NBRx was 2029 and the only plan beyond that is a crystal polymer plan. So my question is are you intending to use 195 to be a first-line regimen in TRK setting or is that still more of a duration of therapy? So I'm just trying to understand the patent dynamic as we model then to the out?

**Kevin Hern**

Okay. Thanks, Umer. We'll have Dan start off with the valuation. Josh, if you want to add in. And then, we'll go to Levi for the number of identified patients for TRK. And then, Dan, maybe on the patent at the end. Thank you.

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**Daniel M. Skovronsky** - *Eli Lilly and Company - Senior VP for Science & Technology & President of Lilly Research Labs*

Yes. Thanks, Umer, for those questions. So you're right in that the driver for this deal, the major contributor to value is indeed the RET program. The TRK program is also very significant, however. But obviously, in deals of this kind, it's the late-stage assets that drive value. So we're excited about those 2 assets. The BTK inhibitor, I think is potentially an upside. It's very early in development, so we have to wait and see some data from that. I think in addition to the 4 clinical assets, that's the TRKs — the 2 TRK inhibitors, the RET inhibitor and the BTK inhibitor, we're also encouraged by the pipeline potential here and the ability to continue to follow this pattern of identifying biologic tumor dependencies genetically and then targeting them with inhibitors in specific patient populations and there could be more to come in that direction as well.

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**Levi Garraway** - *Eli Lilly and Company - SVP of Global Development & Medical Affairs - Oncology Business*

Yes. So Umer, thanks for the question on the incidence. As you pointed out, there's a range of tumors that have been identified to have TRK fusions and they can be in a range of a couple of percent down to maybe 0.5%. But overall, on average, we estimate roughly the worldwide incidence of Vitrakvi — of TRK fusions may be around 10,000 give or take. But obviously, the numbers are hard to get precise because of the range of incidence.

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**Daniel M. Skovronsky** - *Eli Lilly and Company - Senior VP for Science & Technology & President of Lilly Research Labs*

And then final and third question was around the rationale for LOXO-195, that's the follow-on TRK inhibitor for Vitrakvi. And clearly, here the idea is that this is for patients who acquire resistance to a TRK inhibitor and then you can hit them with this molecule. But again, like the BTK inhibitor, this is still quite early in development. And so we have to wait and see how the data play out to figure out what's the best clinical setting to use this in.

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**Kevin Hern**

Thanks, Dan.

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**Operator**

And next we'll go to the line of Louise Chen.

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**Louise Alesandra Chen** - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

First question I had was in this deal, you're pursuing target oncology. So what is Lilly's R&D and commercial philosophy for its oncology franchise now that you have Loxo? Where do you think your leadership in oncology will reside? And then my second question was — is on LOXO-292. What's the market opportunity here in terms of potential sales and who would you compete with? And what is your competitive advantage versus those other companies?

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**Anne E. White** - *Eli Lilly and Company - Senior VP & President of Lilly Oncology*

Yes. So on the question of the synergy here, we — this is clearly part of our oncology strategy that we set forward a year ago. And so we've said that clear focus for Lilly Oncology is targeting tumor dependencies and genetically defined cancers. So we've been looking for opportunities like this, so we think there's a lot of synergy. We've been incredibly impressed with the team at Loxo, both what they've done and how they've done it. So we're really looking forward to the synergies between our 2 teams working together. So there's intention to retain that team and continue to work with them as we look forward to the pipeline that Dan described. Really, again, it also aligns to our goal of first and best-in-class medicines moving forward. And so we're excited about that opportunity. And this just brings a strong portfolio to even they launched and then late phase and also midterm portfolio. So I think the leadership teams have synergy. I think the portfolio has a great deal of synergy and we're excited to work closely with Loxo.

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**Kevin Hern**

And on LOXO-292, the commercial marketing opportunity...

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**Daniel M. Skovronsky** - *Eli Lilly and Company - Senior VP for Science & Technology & President of Lilly Research Labs*

For competitors.

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**Kevin Hern**

For competitors?

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**Anne E. White** - *Eli Lilly and Company - Senior VP & President of Lilly Oncology*

Yes. So on 292, obviously, there are competitors out there. We believe that we have a very strong molecule here in 292. It's going to be the first in class, ahead of the competition. And it's got a very strong efficacy profile and then also, a very robust safety profile, one that we think will be well tolerated by patients. So we think we have a very strong asset. We have a very strong commercial talent in Lilly, Lilly Oncology, particularly in places like lung cancer. So we're looking forward to leveraging that opportunity. I think I'll have Levi talk a little bit about the efficacy data.

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**Levi Garraway** - *Eli Lilly and Company - SVP of Global Development & Medical Affairs - Oncology Business*

Sure. So certainly on the efficacy side, as we mentioned, high efficacy in lung cancer, 68% response rate. In thyroid cancer, the response rate is anywhere from 59% to 78%. Again, duration of therapy is early, but almost all patients are still on therapy, so certainly, from an efficacy standpoint, very exciting. And we think that the duration of therapy in the fullness of time may be benefited by the safety profile, which right now seems quite favorable. So overall, as Anne mentioned, it's early but certainly has characteristics potentially of first and best-in-class medicine, which makes us very excited.

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**Kevin Hern**

Thanks, Levi.

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**Operator**

And next we'll go to the line of Seamus Fernandez.

**Seamus Christopher Fernandez** - *Guggenheim Securities, LLC, Research Division - Senior Analyst of Global Pharmaceuticals*

So maybe just first off, can you guys give us a general sense of the breakup fee and maybe how competitive the process was? And then separate question really is more on the market and how we should be thinking about it? First, on LOXO-292, can you just give us a sense of how you anticipate this market developing relative to the, say, ALK inhibitor market? I know that the 2 might be viewed as similar, but that market took a while to develop. And then just quickly on the currently approved asset, Vitrakvi, can you just help us understand without an FDA approved test, how do you see that market developing? And when do you anticipate an FDA-approved test being available?

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**Kevin Hern**

Thank you. So we'll start off with Josh.

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**Joshua L. Smiley** - *Eli Lilly and Company - Senior VP & CFO*

Thanks, Seamus. First, as it relates to the competitiveness of the process, Loxo, of course, will have to file with the SEC and you'll be able to read whatever's happened there, so I can't really comment there. What I can tell you is this is an asset that we're very excited about for the reasons we've discussed. We've looked at it. And I think we made an offer that we thought was represented fair value for the company and were able to move, I think, swiftly and collaboratively with the company. So we're happy with where we are and think this represents good value for all involved. And I think as you look up at breakup fees and other, I think they're standard types of agreements here. Again, we're really excited about where we are and looking forward to closing this transaction as quickly as possible and moving forward for patients.

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**Kevin Hern**

Okay. Thanks, Josh. Dan will take the second question and then Levi will take Seamus' third question.

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**Daniel M. Skovronsky** - *Eli Lilly and Company - Senior VP for Science & Technology & President of Lilly Research Labs*

Yes. Thanks, Seamus. So your second question was around 292 and how the diagnostic testing uptake will evolve. I think in the case of 292, we have to think about really 3 different tumor types and then possibly a fourth, which is what we consider like a long tail of tumors that all have a lower incidence of RET fusion. So starting with the 3 big ones, the biggest, of course, is lung. In lung, the uptake of testing could be much faster, driven by currently existing therapies as you point out and the already widespread use of genetic — genotyping in lung cancer as well as the higher prevalence of RET fusions in lung cancer. So I think that's the biggest opportunity for this molecule and the one that could develop the fastest. The other one that could develop very quickly is medullary thyroid carcinoma. And there, it's because the RET fusions are so common; 60%, 75% of medullary. Medullary is a rarer tumor type in thyroid, and I anticipate that could also go very quickly. The third big one that may take a little more time or effort to develop is papillary. Of course, papillary thyroid carcinoma is the most common type of thyroid cancer. And here, of course, we're talking about advanced stage, treatment-resistant patients. And the prevalence of activating — the prevalence of the RET abnormality here is 10% to 20% in papillary thyroid carcinoma. And so that would be a new idea for testing here. But I think we could — we can make that happen as well. And then finally, you get to all of the other tumor types where there could be less than 1% incidence of RET fusions or activating mutations. And here, I think it could take a little time. We don't yet have much data. There's just a few patients who have responded with RET fusions in different tumor types. But that represents, I think, a tremendous upside even beyond these 3 major tumor types as testing comes into plan in those tumor types.

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**Levi Garraway** - *Eli Lilly and Company - SVP of Global Development & Medical Affairs - Oncology Business*

Yes. And just going into the issue of Vitrakvi and FDA-approved tests in general. So already — there are already mutational profiling approaches that have FDA approval for these kind of testing that, of course, include both the TRK and the RET fusions that we'd be interested in. In general,

we've seen over the course of time — first of all, oncology in general is moving more and more towards genetic and molecular profiling. And certainly, if there's an effective medicine that can be leveraged if one of these alterations is discovered, that tends to be an additional boost in uptake and impetus to develop these tests. There are a number of other companies out there that are developing these kinds of diagnostics. So we think that the direction of the field and already early availability of tests that could be used in this regard will continue to drive adoption over time.

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**Kevin Hern**

Thanks, Levi.

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**Operator**

And next, we'll go to the line of Geoff Meacham.

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**Geoffrey Christopher Meacham** - *Barclays Bank PLC, Research Division - MD & Senior Research Analyst*

Just one on 305. When you look at the opportunities moving upstream in BTK, have you guys looked at that? Is that part of the strategy? Obviously, it looks like you're going after patients that have acquired resistance? And then maybe more broadly, when you look at the portfolio, the pipeline, is — are there opportunities to combine with Lilly's existing portfolio more broadly from a 2-drug combo, either immuno-oncology, or just how are you thinking about leveraging the assets down the road with what you have today?

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**Kevin Hern**

Geoff, so we'll have Levi take the 305 question and Dan will talk about the portfolio implications.

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**Levi Garraway** - *Eli Lilly and Company - SVP of Global Development & Medical Affairs - Oncology Business*

Of course, the mechanism of action here, it can target the single most prominent resistance mutation in BTK, the C481 mutation, which — already, the estimates could be that anywhere between 20% and maybe as high as 50-plus percent of patients can have that alteration. So already, we think that could be an interesting opportunity. It's also active against the wild-type BTK, and you may know that there's a fair number of patients who are not tolerant of the first-generation BTK inhibitor. So that could be an opportunity for a medicine like this. So obviously, it's early in development, but we like the profile of this medicine, and we like the opportunities both in the acquired resistance setting and potentially in other settings as well.

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**Daniel M. Skovronsky** - *Eli Lilly and Company - Senior VP for Science & Technology & President of Lilly Research Labs*

Great. Thanks, Geoff. And I think with regards to your question about synergies with our internal portfolio, I think we can think about this in 2 different ways. So one is targets that we have programs against internally that are going to require the same type of genetic testing and profiling and personalization for patients where that is going to become more and more common. We have a number of such programs in our early stage portfolio. As those develop, there could be synergy there. The others are more the biological synergy that I think you're alluding to. And so far, what we've seen is in patients where RET or TRK, for example, are the drivers genetically fused or activating mutations that the monotherapy seems to be highly efficacious. Now there could be other patients that have overexpression or activation of these pathways that could require a combination with other molecules including certain things we have in our portfolio. So it's an area of interest for us. There is not a lot of data there that extends beyond preclinical data. Certainly, not a driver for valuation in the deal, but potentially an upside as biology plays out.

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**Kevin Hern**

Thanks, Dan.

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**Operator**

And now we'll go to the line of John Boris.

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**John Thomas Boris** - *SunTrust Robinson Humphrey, Inc., Research Division - MD*

Congrats on the transaction. Most of my scientific questions have been answered, but we'd like to just ask Josh how he's thinking about the pros, cons of treating this from an accounting standpoint as an asset acquisition versus business combination? And then on the incremental R&D spends kind of be required and impact on margin? So just anything you can potentially provide directionally in terms of magnitude of impact going forward?

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**Joshua L. Smiley** - *Eli Lilly and Company - Senior VP & CFO*

Thanks, John, as it relates to the accounting, we'll work with our auditors and make the decision that makes the most sense. I think from an accounting perspective, pros and cons are kind of tough to talk about, I think. But overall, if it's an asset acquisition, you end up with in-process R&D, a significant portion of the acquisition cost would go to in-process R&D and be expensed immediately through the GAAP income statement. If it's a business combination, we capitalize much of the value and assess it on a periodic basis for impairment. So the biggest, I think, difference you would see is how we treat the in-process — or the development assets I think for Vitrakvi. I think, in either case, we ascribe value to that and put it on the balance sheet. I think from a non-GAAP P&L perspective, really, the impacts you'll see would be the incremental financing cost here. And as I mentioned, very consistent with the strategy we've laid out over the last year, we've been planning to deploy capital to external innovation and so, to some degree, some of this was already embedded in our 2019 guidance. But I think from an operating income perspective, the thing you'll see immediately would be some pressure on our R&D range that we've provided in 2019. I think as we look at progressing the portfolio, both continuing to support Vitrakvi as well as the pipeline assets that we talked about, you're looking at probably in the range of $200 million or so a year of incremental R&D now on our total R&D budget range of somewhere in the 5%, 5.7% or so. This isn't a significant additional piece, but it's important. So that's where I think you'll see the impact in the immediate term. But as you know, with these assets, we can — you can launch quickly and if successful, scale pretty quickly. So as I've mentioned, we see positive cash flow and accretion from this opportunity beginning in the early parts of the 2020s.

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**John Thomas Boris** - *SunTrust Robinson Humphrey, Inc., Research Division - MD*

And then the — just very quickly, if I could slip one in, the breakup fee as a percent of total value of the deal?

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**Joshua L. Smiley** - *Eli Lilly and Company - Senior VP & CFO*

Again, standard looks relative to other deals here. So again, assume we're not going to be in that position but nothing unusual here. There is a standard breakup fee.

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**Operator**

And now we'll go to the line of David Risinger.

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**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Congrats on the deal as well. I just wanted to ask about the Bayer partnership. I was hoping that you could explain that further and whether there is an opportunity for Lilly to replace that after acquiring Loxo?

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**Anne E. White** - *Eli Lilly and Company - Senior VP & President of Lilly Oncology*

Yes. We very much want to continue that partnership with Bayer. I think it's been quite successful between Loxo and Bayer and so — and what they do now is co-promote Vitrakvi and I'm sure the development as well on LOXO-195. And so we're looking to continue that and so we'll obviously be starting conversations with Bayer on that to support that. We believe that Lilly brings a great deal of strength to this partnership in addition to what Loxo has already done. We have a team of diagnostic experts at Lilly. We obviously have a great deal of strength in many of the tumor types that we're working in and we've also demonstrated over many years now our partnership strength, our ability to work with other large and small pharma very successfully. So we think that we bring a lot to the Bayer and Loxo partnership. And so we'll definitely be working towards that goal over time. The way that the partnership works is that Loxo leads U.S. regulatory, global development and there's a commercial lead with lab directors and pathologists, whereas Bayer leads really commercial and regulatory outside the U.S. primarily. So we're looking to continue that partnership on Vitrakvi and then 195, if Bayer agree.

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**Kevin Hern**

Thank you, Anne.

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**Operator**

And now we'll go to the line of Vamil Divan.

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**Vamil Kishore Divan** - *Crédit Suisse AG, Research Division - Senior Analyst*

Most of mine have also been answered, but a couple last ones here. One, just around looking forward, you mentioned that this does give you flexibility to pursue other licensing and M&A. Maybe you could just talk about now that you've done this deal, which is obviously pretty large, from a Lily historical perspective, should we look for things more on this size or smaller or larger? And is oncology still an area that you'd expect to do additional transactions or maybe focus on some of the other areas? And then the second question was mentioned earlier, just about the Loxo leadership team and the synergies there with Lilly team. Is there any sort of retention strategies put in place that you can discuss at this point to maintain the team from Loxo?

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**Kevin Hern**

Thanks, Vamil. We'll have Dave address your first question and then Anne will talk about the Loxo leadership.

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**David A. Ricks** - *Eli Lilly and Company - Chairman, CEO & President*

Yes, thanks. We see this acquisition as completely in line with what we've been talking about all along, which is really a strong interest in focusing on our core therapeutic areas, enhancing our pipeline prospects within those. And in this case, although you're right, the total size of the acquisition, $8 billion, is bigger than what we've done before, I think it's in the range of what we've been talking about. And in this case, you have 4 either clinical or recently approved medicines in one package, which is a bit unique for us, along with, as Dan mentioned, a potential innovation platform to continue to look for these types of genetic mutations in cancer and exploit those with kinase inhibitors and other approaches, so all that to us made sense in integrating to acquire Loxo. Will we focus now outside of oncology, having done this larger transaction in oncology, larger for us? The answer to that is we'll continue to look in oncology as well as other core therapeutic areas. It just so happens, in oncology, there is many more

opportunities to look for biotech acquisition and pipeline additions because of how the science is really changing the treatment of cancer and so many venture-backed companies exploiting that, but that doesn't mean we'll exclude our other areas of interest either. Immunology is an active area, of course. And diabetes and neuroscience, where we have a strong historical presence and we'll continue to look to complement our work in those areas as we did last year. So this is something that I would say going forward isn't out of range to do again. At the same time, we're not focused on scale. We're focused on value-creating pipeline additions.

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**Anne E. White** - *Eli Lilly and Company - Senior VP & President of Lilly Oncology*

Yes. And on the leadership team at Loxo, I think it's important to take a minute and recognize what they've done and what they've accomplished here in 5.5 years. It's really quite remarkable. So huge, I think, congratulations goes to Josh Bilenker and Jake Van Naarden for their leadership at Loxo. And we very much want that to continue, so we've already started conversations with them about what that might look like. And obviously, we need to work through those details. They've expressed their interest in following through, and I think you can tell, for those that you have met with them, there's a passion for what they've created here is something that's truly motivating to them and they've expressed that repeatedly to us. We share that enthusiasm. So I think our goals are aligned to really reach as many patients with these mutations as we can and really help as many patients as possible, and they are very interested and motivated by that as well as they have been for the last 5.5 years. So I think our leadership goals are synergistic. We very much want to tap into what they've done and what they've created and how we can apply those lessons to our overall Lilly Oncology portfolio. So more to come, but we're very hopeful that this partnership will continue in this way.

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**Kevin Hern**

Thanks, Anne. And with that, we will turn the call back over to Dave. We appreciate your questions today.

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**David A. Ricks** - *Eli Lilly and Company - Chairman, CEO & President*

Thanks, Kevin, and we appreciate your interest in our company as well as dialing in to this call this morning, early West Coast time for us at J.P. Morgan. Lilly has a diverse and durable revenue outlook. We have strong global commercial capabilities and has recently launched new products into some of the most promising classes in the entirety of biopharma, placing us in the early phases of a prolonged period of volume-driven growth for our company. As we build on that strong foundation, we continue to invest in R&D and bolster — in order to bolster our pipeline with first-in-class and best-in-class opportunities like Loxo Oncology. Today's announcement builds upon a series of transactions over the past 12 months, which will make Lilly's portfolio increasingly relevant to oncologists and the patients they treat and continue our strategic commitment to develop new medicines that will transform care in some of society's most serious illnesses. Thank you for calling in today. Have a good one, and we'll talk soon.

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**Operator**

Ladies and gentlemen, that does conclude our conference for today. Thank you for your participation and for using AT&T teleconference. You may now disconnect.

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***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.*

***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 (the "Solicitation/Recommendation Statement") 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.*

*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.*