

# Fourth Quarter and Full Year 2018 Financial Results

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Exelixis, Inc.  
NASDAQ: EXEL

Tuesday, February 12, 2019



# Safe Harbor Statement

This presentation, including any oral presentation accompanying it, contains forward-looking statements, including, without limitation, statements related to: Exelixis' belief that cabozantinib's best-in-class TKI profile can continue to drive strong growth in the face of emerging competition from ICI-based therapies; Exelixis' plans for additional pivotal trials; Exelixis' continued financial performance, including the growth of revenues from product sales, collaboration milestones and royalties, and rigorous management of expenses to generate free cash to reinvest in the business; Exelixis' commitment to staying focused and delivering on goals for both patients and stockholders; Exelixis' financial guidance for 2019 costs of goods sold, R&D and SG&A expenses (including non-cash expenses related to stock-based compensation), and effective tax rate; Exelixis' belief that it has strong momentum in the RCC market heading into 2019 as a result of observed sequencing trends, including the increase in second-line RCC patients treated with CABOMETYX following ICI therapy; the commercial opportunity for cabozantinib as a treatment for patients with HCC and the potential for overlap between RCC and HCC subscribers to drive early adoption; Exelixis' expectation that the HCC drug-treated population will increase significantly by 2025; the anticipated timing for receipt of a \$20 million milestone payment from Daiichi Sankyo upon the first commercial sale of MINNEBRO in Japan; Exelixis' eligibility for additional commercialization milestones and low double-digit royalties on sales of MINNEBRO; the potential for Roche to submit additional regulatory filings for cobimetinib later in 2019, if data from the IMspire 150 TRILOGY and IMspire170 trials are supportive; Exelixis' broad development and lifecycle management plan for cabozantinib, including multiple pivotal clinical trials evaluating cabozantinib in combination with ICIs or other anti-cancer agents across a variety of indications and tumor types; Exelixis' plans to initiate a phase 3 pivotal trial evaluating cabozantinib in combination with nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in treatment-naïve RCC; Exelixis' anticipation to begin additional late-stage studies in bladder cancer and NSCLC; Exelixis' plan to initiate a phase 1 trial of XL092 that will include dose-escalation and expansion cohort stages, and if warranted by the trial data, to pursue both single-agent and combination approaches for XL092; Exelixis' belief that its notable regulatory, commercial and financial performance in 2018 provides a strong platform for building its product portfolio with future cabozantinib label-enabling trials and adding new product opportunities through internal and external research and discovery efforts; Exelixis' focus on targeting the entire RCC population and working towards a future where every eligible patient receives CABOMETYX at some point in their journey from first- to third-line treatment; Exelixis' belief that front-line ICI combinations could create second- and later-line growth opportunities for years to come; Exelixis' belief that the phase 1b COSMIC-021 trial evaluating the combination of cabozantinib and atezolizumab could inform a potential third wave of pivotal trials; and Exelixis' plans to use its growing cash position and financial depth to advance next-generation compounds, such as XL092, and for strategic transactions, licensing or acquiring compelling assets that are valued appropriately. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the degree of market acceptance of CABOMETYX, COMETRIQ, COTELLIC and MINNEBRO in the territories where they are approved, and the availability of sufficient coverage and adequate reimbursement for these products; the effectiveness of CABOMETYX, COMETRIQ, COTELLIC and MINNEBRO in comparison to competing products; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; the potential failure of cabozantinib, cobimetinib, esaxerenone and other Exelixis product candidates, both alone and in combination with other therapies, to demonstrate safety and/or efficacy in clinical testing; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationships with its collaboration partners, including their pursuit of regulatory approvals for partnered compounds in new indications, their adherence to their obligations under relevant collaboration agreements and the level of their investment in the resources necessary to complete clinical trials or successfully commercialize partnered compounds in the territories where they are approved; risks and uncertainties related to regulatory review and approval processes, including that regulatory authorities may not approve Exelixis' products as treatments for the indications in which approval has been sought; Exelixis' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating cabozantinib, cobimetinib or esaxerenone; Exelixis' dependence on third-party vendors for the manufacture and supply of its products; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of Exelixis' marketed products; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 1, 2018, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Annual Report on Form 10-K expected to be filed with the SEC on February 22, 2019. All forward-looking statements in this presentation are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein.

This presentation includes certain non-GAAP financial measures as defined by the SEC rules. As required by Regulation G, we have provided a reconciliation of those measures to the most directly comparable GAAP measures, which is available in the appendix.

# Today's Agenda

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## Introduction

**Susan Hubbard**

EVP, Public Affairs and Investor Relations

## Overview

**Michael M. Morrissey, Ph.D.**

President and CEO

## Financial Results & Guidance

**Chris Senner**

EVP and CFO

## Commercial Update

**PJ Haley**

SVP, Commercial

## Pipeline Update

**Peter Lamb, Ph.D.**

EVP, Scientific Strategy and CSO

## Development Update

**Gisela Schwab, M.D.**

President, Product Development and Medical Affairs and CMO

*Q&A with full team to conclude the call*

# Overview

Michael M. Morrissey, Ph.D.  
President and CEO



# Fourth Quarter 2018 Highlights

## Growth in Revenues, Earnings, and Cash

Cabozantinib net franchise revs of \$176M (Q4); Non-GAAP Q4 net income of \$116M or \$0.37/share, Cash \$851.6M\*

## Continued Performance of CABOMETYX in RCC

The best-in-class TKI for advanced RCC; the preferred TKI for previously untreated and refractory patients

## Regulatory and Clinical Progress

Approval and launch of CABOMETYX in 2L HCC; three pivotal trials in progress, with more anticipated

## Reinitiated Discovery Efforts

Active IND for XL092; additional discovery work and BD process to evaluate in-licensing opportunities ongoing



*On a mission to help patients  
with cancer recover stronger  
and live longer*



\*Includes cash and cash equivalents, short- and long-term investments, and long-term restricted cash and investments.  
A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation

RCC = renal cell carcinoma; TKI = tyrosine kinase inhibitor 2L HCC = second-line hepatocellular carcinoma; IND = investigational new drug; BD = business development

# Strength Across the Business Propels Us into 2019

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- Seek to grow revenues from product sales, collaboration milestones and royalties, while managing our expenses in a rigorous fashion
- Generate free cash to reinvest in our business to build long-term, sustainable growth
- Committed to staying focused and delivering on our goals for patients and stockholders

# Financial Update

Chris Senner  
EVP and CFO



# Financial Highlights: Q4 2018

(in millions, except for per share amounts)

|                                             | <u>Q4'17</u>     | <u>Q3'18</u>     | <u>Q4'18</u>     | <u>YoY Delta</u> | <u>QoQ Delta</u> |
|---------------------------------------------|------------------|------------------|------------------|------------------|------------------|
| <b>Total revenues</b>                       | <b>\$120.1 M</b> | <b>\$225.4 M</b> | <b>\$228.6 M</b> | <b>+90%</b>      | <b>+1%</b>       |
| <b>Cost of goods sold</b>                   | <b>\$4.2 M</b>   | <b>\$7.4 M</b>   | <b>\$7.4 M</b>   | <b>+76%</b>      | <b>+0%</b>       |
| <b>R&amp;D expenses</b>                     | <b>\$32.2 M</b>  | <b>\$44.7 M</b>  | <b>\$57.3 M</b>  | <b>+78%</b>      | <b>+28%</b>      |
| <b>SG&amp;A expenses</b>                    | <b>\$46.2 M</b>  | <b>\$48.1 M</b>  | <b>\$52.4 M</b>  | <b>+13%</b>      | <b>+9%</b>       |
| <b>Total operating expenses *</b>           | <b>\$82.6 M</b>  | <b>\$100.2 M</b> | <b>\$117.0 M</b> | <b>+42%</b>      | <b>+17%</b>      |
| <b>Other income (expense): net</b>          | <b>\$1.5 M</b>   | <b>\$3.8 M</b>   | <b>\$4.8 M</b>   | <b>+220%</b>     | <b>+26%</b>      |
| <b>Provision for income taxes</b>           | <b>\$(0.4) M</b> | <b>\$(2.3) M</b> | <b>\$243.7 M</b> | <b>n/a</b>       | <b>n/a</b>       |
| <b>Net income *</b>                         | <b>\$38.5 M</b>  | <b>\$126.6 M</b> | <b>\$360.1 M</b> | <b>+835%</b>     | <b>+184%</b>     |
| <b>Net income (loss) per share, diluted</b> | <b>\$0.12</b>    | <b>\$0.41</b>    | <b>\$1.15</b>    | <b>+858%</b>     | <b>+180%</b>     |
| <b>Ending cash and investments **</b>       | <b>\$457.2 M</b> | <b>\$750.3 M</b> | <b>\$851.6 M</b> | <b>+86%</b>      | <b>+14%</b>      |

\* Amounts may not sum to total due to rounding

\*\* Cash and investments include cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments. Long-term restricted cash and investments totaled \$1.1 million as of December 31, 2018; Short- and long-term restricted cash and investments totaled \$5.2 million as of December 31, 2017.

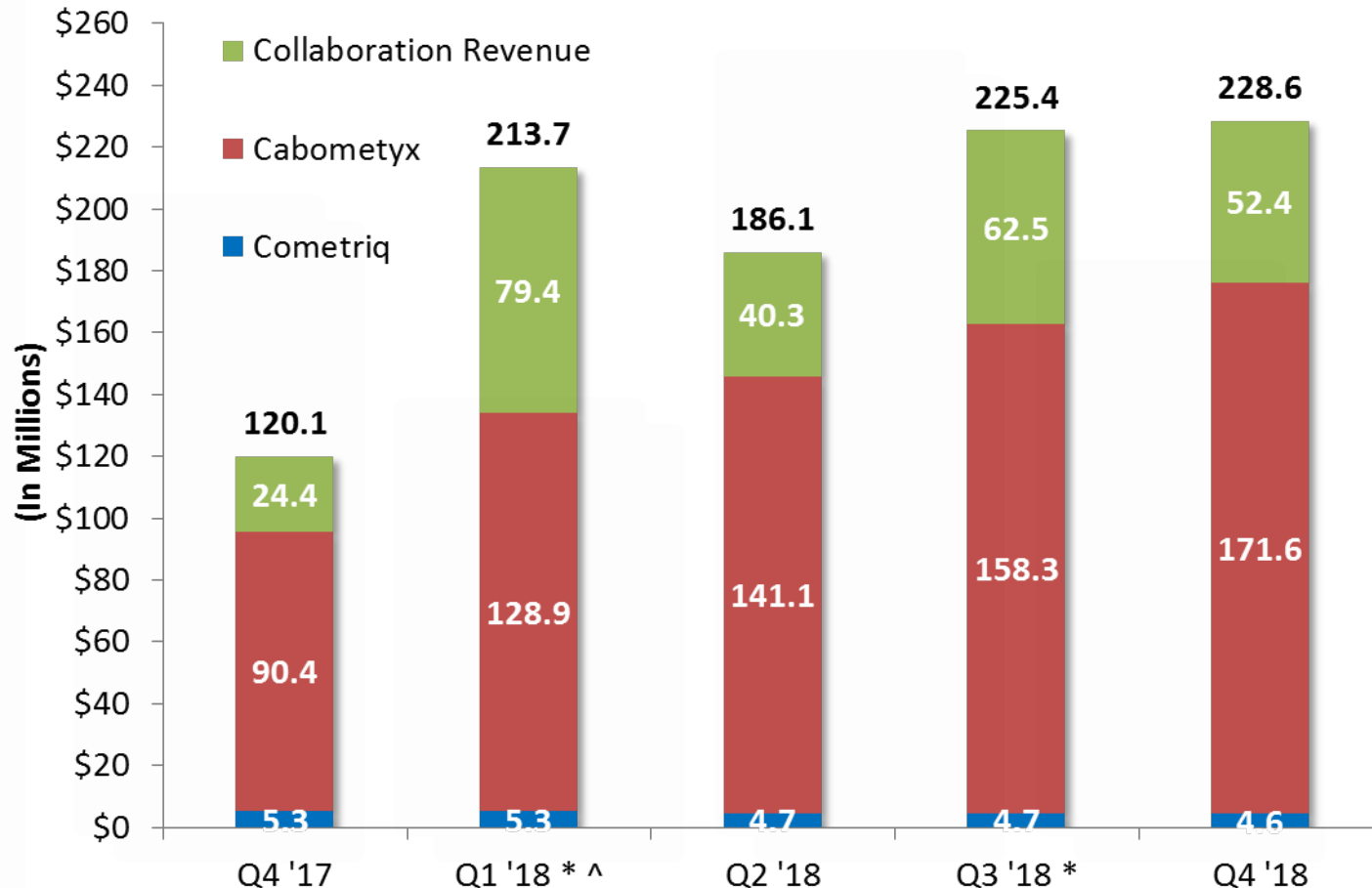
# Financial Highlights: Fiscal Year 2018

(in millions, except for per share amounts)

|                                             | <u>FY 2017</u>   | <u>FY 2018</u>   | <u>YoY Delta</u> |
|---------------------------------------------|------------------|------------------|------------------|
| <b>Total revenues</b>                       | <b>\$452.5 M</b> | <b>\$853.8 M</b> | <b>+89%</b>      |
| <b>Cost of goods sold</b>                   | <b>\$15.1 M</b>  | <b>\$26.3 M</b>  | <b>+74%</b>      |
| <b>R&amp;D expenses</b>                     | <b>\$112.2 M</b> | <b>\$182.3 M</b> | <b>+62%</b>      |
| <b>SG&amp;A expenses</b>                    | <b>\$159.4 M</b> | <b>\$206.4 M</b> | <b>+29%</b>      |
| <b>Total operating expenses</b>             | <b>\$286.6 M</b> | <b>\$415.0 M</b> | <b>+45%</b>      |
| <b>Other income (expense): net</b>          | <b>\$(7.3) M</b> | <b>\$13.2 M</b>  | <b>n/a</b>       |
| <b>Provision for income taxes</b>           | <b>\$(4.4) M</b> | <b>\$238.0 M</b> | <b>n/a</b>       |
| <b>Net income</b>                           | <b>\$154.2 M</b> | <b>\$690.1 M</b> | <b>+348%</b>     |
| <b>Net income (loss) per share, diluted</b> | <b>\$0.49</b>    | <b>\$2.21</b>    | <b>+351%</b>     |
| <b>Ending cash and investments*</b>         | <b>\$457.2 M</b> | <b>\$851.6 M</b> | <b>+86%</b>      |

# Q4 2018 Total Revenue

(See press release at [www.exelixis.com](http://www.exelixis.com) for full details)



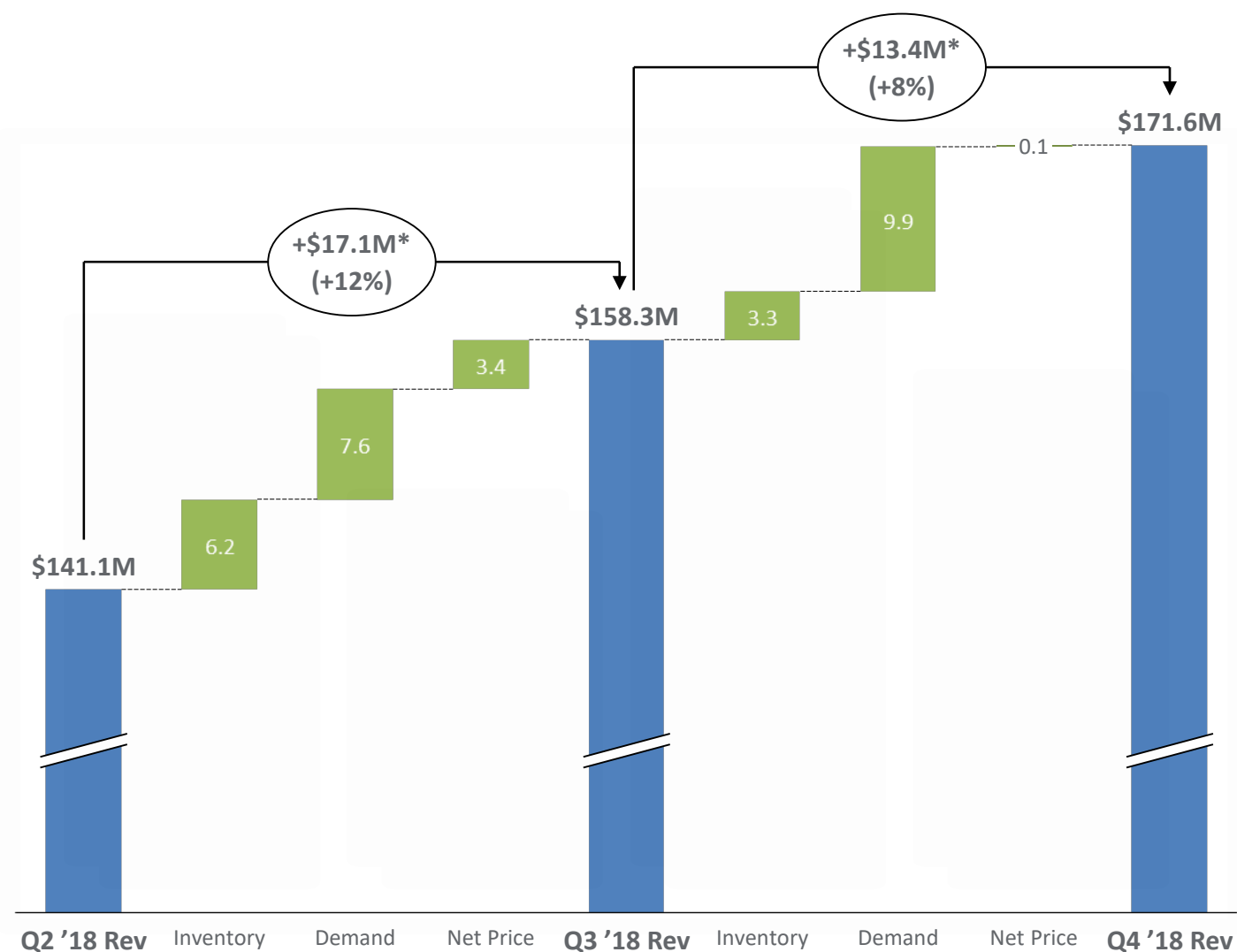
\* Amounts do not sum to total due to rounding

^ Q1 2018 financial results as reported on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 2, 2018, were adjusted to conform to current period presentation resulting in an increase to both Collaboration Revenue and Sales & Marketing Expenses by \$1.4M related to the COTELLIC U.S. Profit Share agreement with Roche. There was no impact to Net Income or EPS.

## Q4 2018 Notes

- ◆ Total revenues of \$228.6M
- ◆ \$176.2M in net product revenues, including \$171.6M in CABOMETYX and \$4.6M in COMETRIQ net product revenues
  - ❖ CABOMETYX product revenue higher in Q4 vs. Q3 due primarily to higher patient demand and change in inventory
- ◆ Collaboration Revenue for Q4 2018 include:
  - ❖ \$18.6M in Milestones from Ipsen
  - ❖ \$12.3M in Royalties from Ipsen
  - ❖ \$9.3M in a Milestone from Takeda
  - ❖ \$8.8M in R&D reimbursements & other
  - ❖ \$3.4M in COTELLIC Profit Share & Royalties

# Cabometyx US Quarterly Net Sales Growth

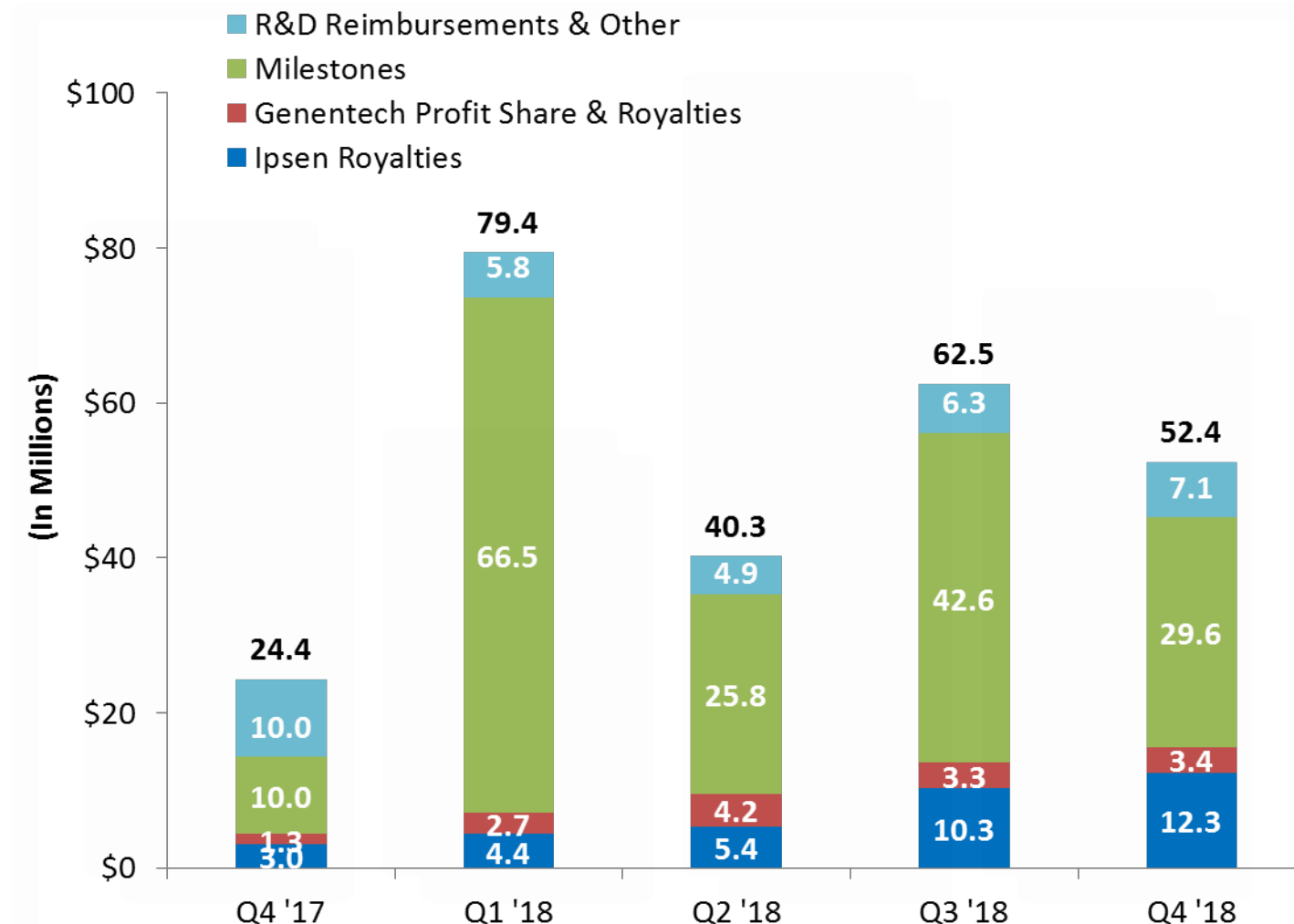


## 2H 2018 Notes

- ◆ Q4 growth of \$13.4M / 8%
  - ❖ ~\$9.9M increase in CABOMETYX patient demand
  - ❖ ~\$3.3M increase in wholesaler inventory
  - ❖ ~\$0.1M increase due to net price:
    - ~\$3.3M from price increase offset by 1.5% point increase in gross-to-net
- ◆ Q3 growth of \$17.1M / 12%
  - ❖ ~\$7.6M increase in CABOMETYX patient demand
  - ❖ ~\$6.2M increase in wholesaler inventory
  - ❖ ~\$3.4M increase due to net price:
    - ~\$3.9M from price increase offset by 0.3% point increase in gross-to-net
- ◆ Over the last two quarters, we have seen an ~700 unit increase in wholesaler inventory, primarily related to an increase in weeks on hand
- ◆ Wholesalers carried more inventory exiting 2018 than what has been seen previously

# Collaboration Revenue Detail

(See press release at [www.exelixis.com](http://www.exelixis.com) for full details)

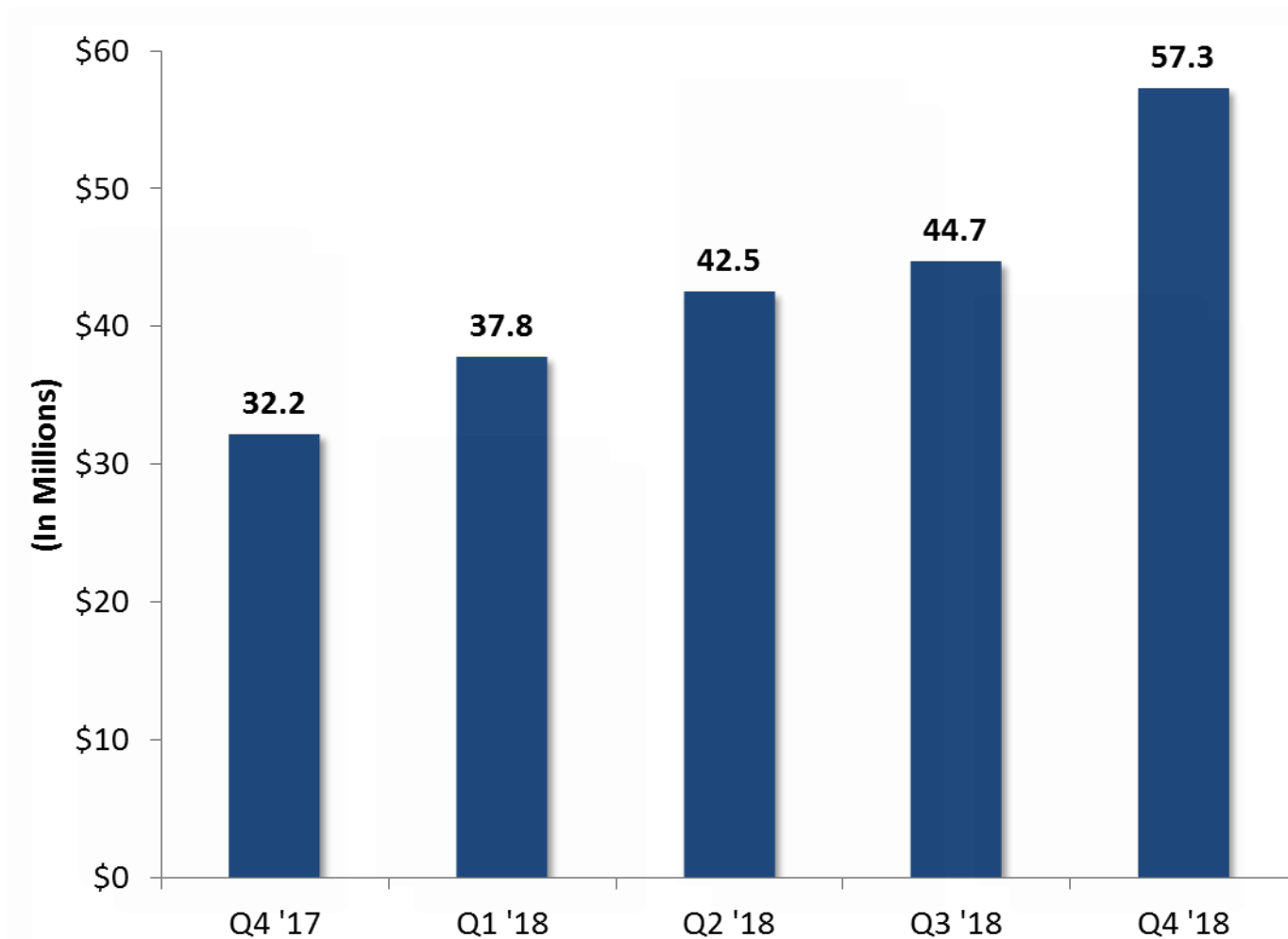


## Q4 2017 – Q4 2018 Notes

- ◆ Ipsen Royalties 22% in 2H 2018 and ~12% from Q4 2017 to Q2 2018
- ◆ Genentech ex-US Cotellic Royalties ~12%
- ◆ Genentech US Profit Share considered revenue starting in Q1 2018
- ◆ Major Milestones by Quarter
  - ❖ Q4 2018: Ipsen Ph 3 Initiation, Takeda Ph 3 Initiation
  - ❖ Q3 2018: Ipsen HCC 2L EU Approval, Ipsen RCC 2L Canada Approval
  - ❖ Q2 2018: Ipsen Sales > \$100M in four consecutive quarters
  - ❖ Q1 2018: Ipsen RCC 1L EU Approval, Daiichi Sankyo NDA Acceptance
  - ❖ Q4 2017: Bristol-Myers Squibb ROR CTA in EU

# Q4 2018 R&D Expense

(See press release at [www.exelixis.com](http://www.exelixis.com) for full details)

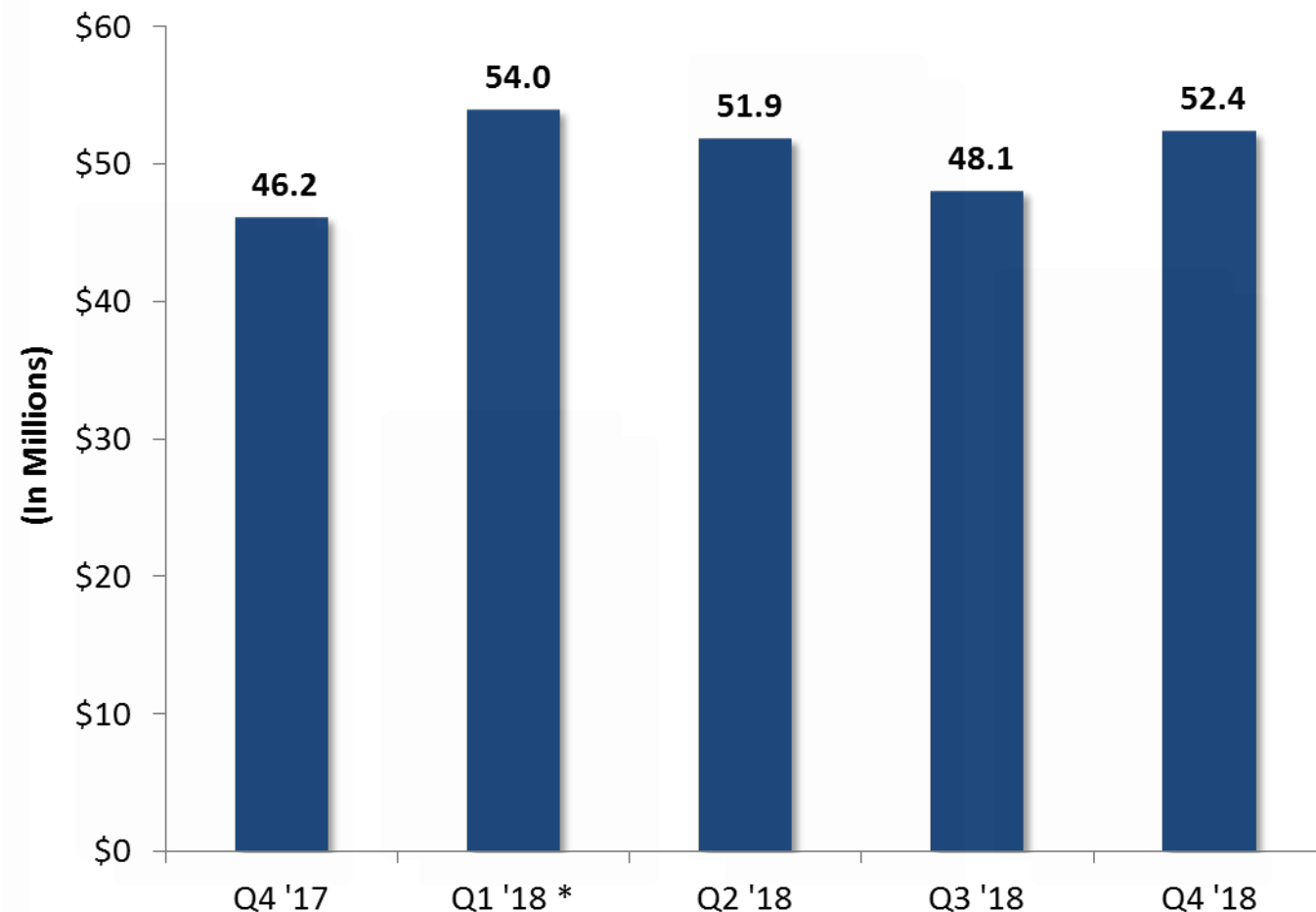


## Q4 2018 Notes

- ◆ R&D expenses of \$57.3M
- ◆ Increase in R&D expenses vs. Q3 2018 primarily a result of headcount additions and higher clinical trials spend
  - ❖ COSMIC-311
  - ❖ COSMIC-312
  - ❖ COSMIC-021
  - ❖ Checkmate 9ER

# Q4 2018 SG&A Expense

(See press release at [www.exelixis.com](http://www.exelixis.com) for full details)

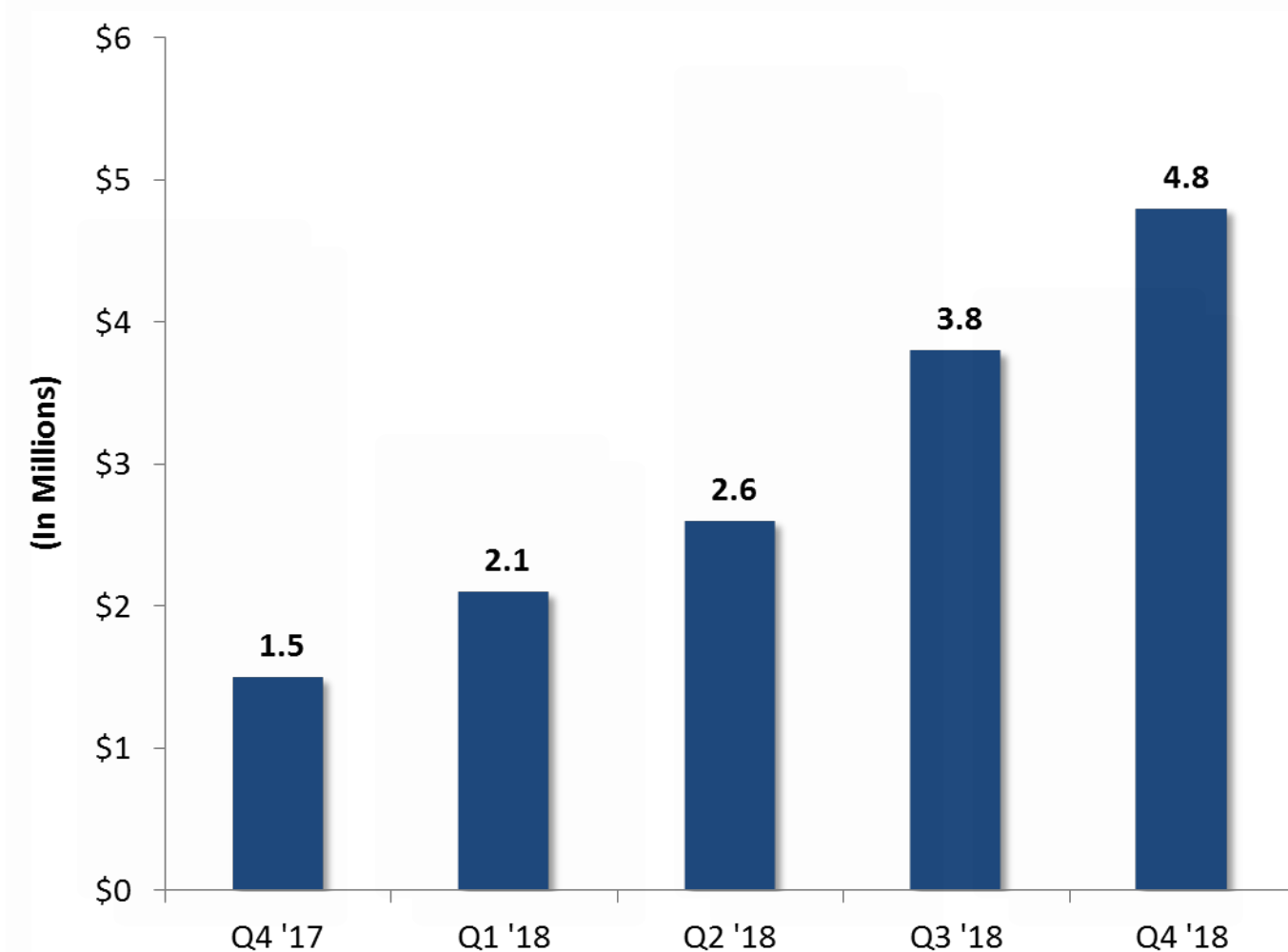


## Q4 2018 Notes

- ◆ SG&A expenses of \$52.4M
- ◆ Increase in SG&A expenses vs. Q3 2018 is a result of higher consulting & outside services, higher stock compensation, and headcount additions

# Q4 2018 Other Income (Expense), net

(See press release at [www.exelixis.com](http://www.exelixis.com) for full details)

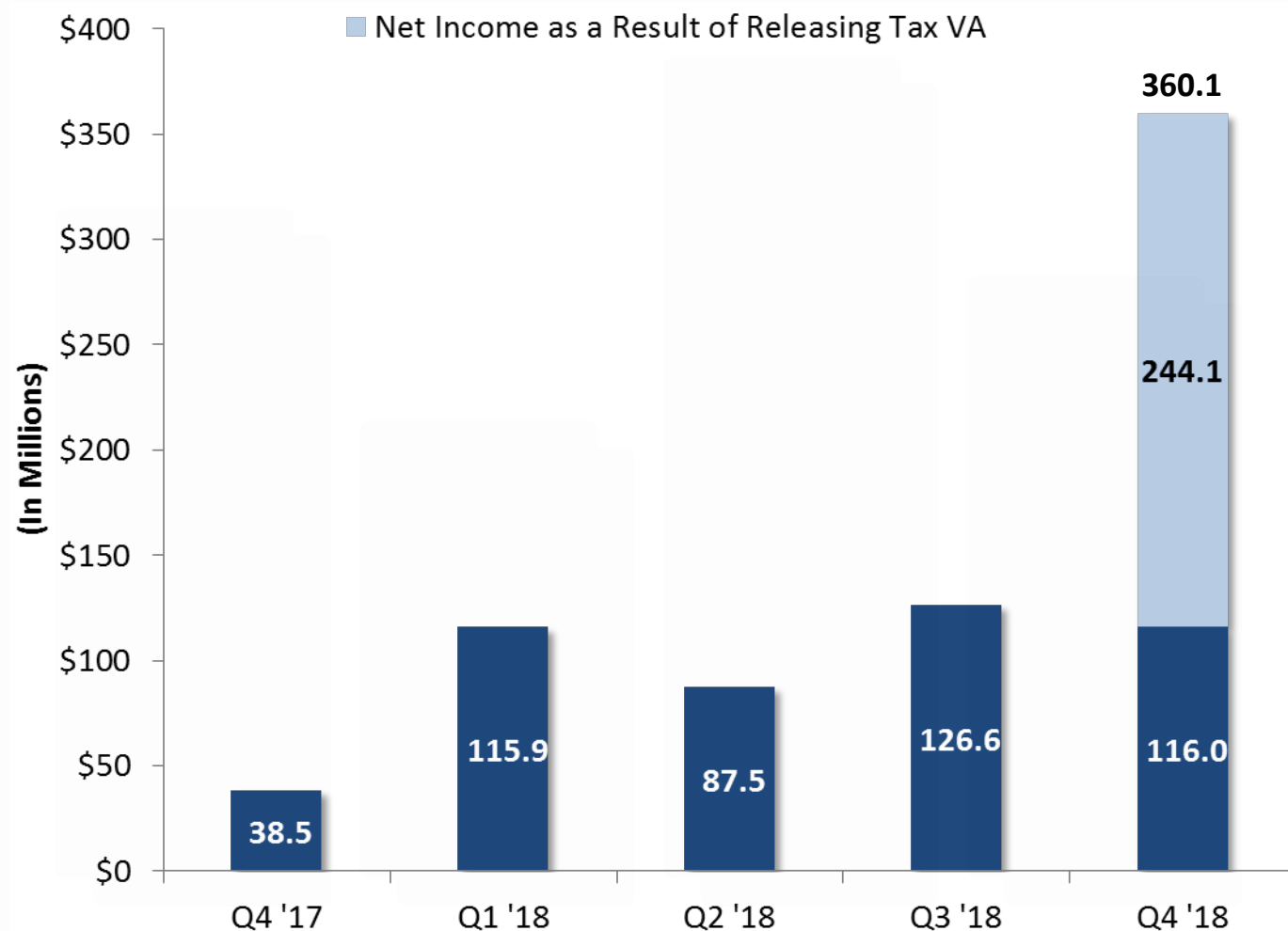


## Q4 2018 Notes

- ◆ Other income (expense), net in Q4 2018 reflects income of \$4.8M, primarily driven by interest income from growing cash balance and higher yields
- ◆ Past five quarters' OI&E primarily reflect interest income

# Q4 2018 Net Income

(See press release at [www.exelixis.com](http://www.exelixis.com) for full details)



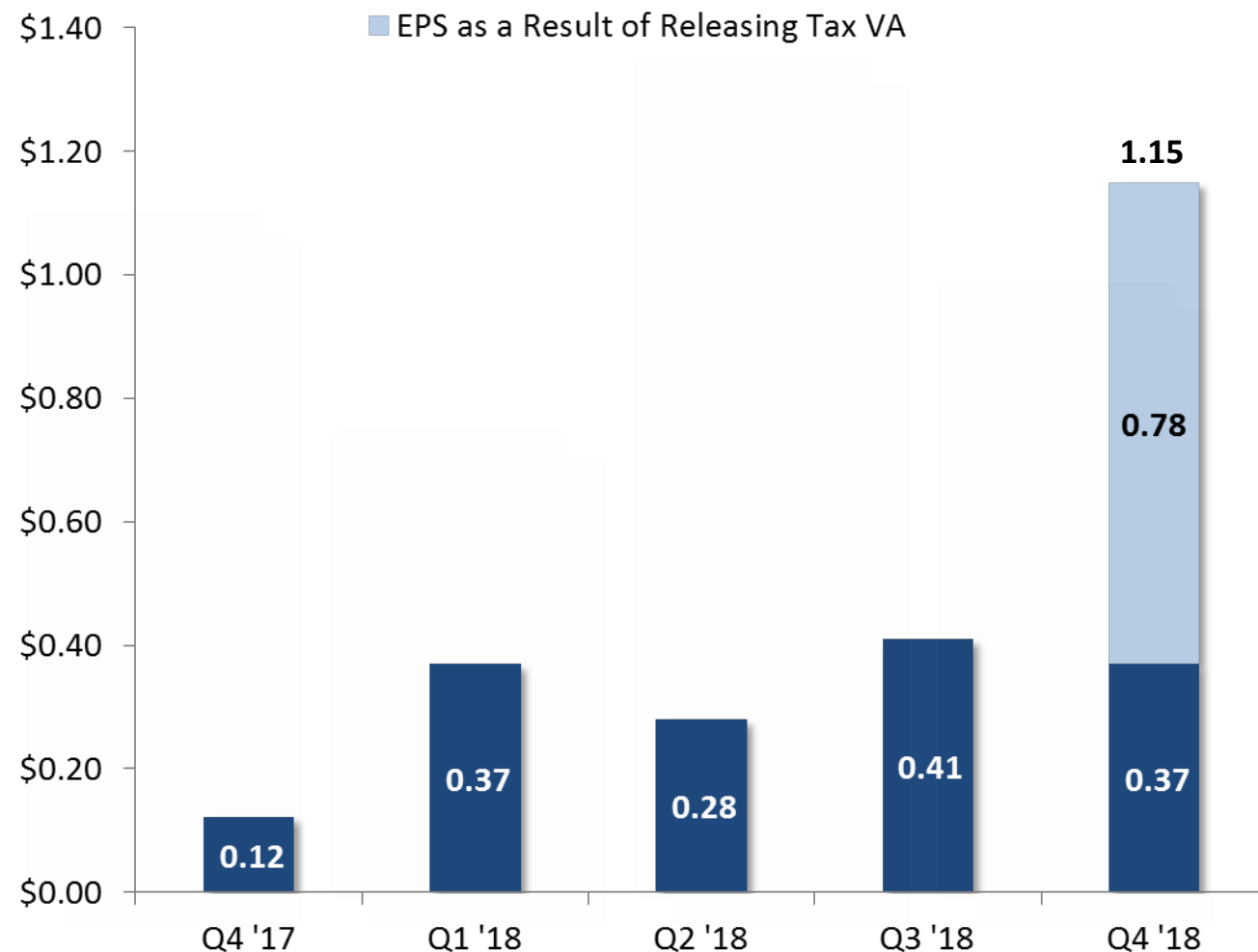
A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.

## Q4 2018 Notes

- ◆ GAAP Net Income of \$360.1M
- ◆ Non-GAAP Net Income of \$116.0M
- ◆ Increase in Net Income vs. Q3 2018 driven primarily by non-cash impact of tax valuation allowance release in Q4 2018, totaling \$244.1M
- ◆ Q4 2018 included collaboration milestones from Ipsen of \$18.6M and from Takeda of \$9.3M
- ◆ Q3 2018 included collaboration milestones from Ipsen of \$41.9M

# Q4 2018 Earnings Per Share, Diluted

(See press release at [www.exelixis.com](http://www.exelixis.com) for full details)



## Q4 2018 Notes

- ◆ GAAP Diluted EPS of \$1.15
- ◆ Non-GAAP Diluted EPS of \$0.37
- ◆ Increase in EPS vs. Q3 2018 driven by non-cash impact of tax valuation allowance release in Q4 2018, totaling \$244.1M
- ◆ Q4 2018 included collaboration milestones from Ipsen of \$18.6M and from Takeda of \$9.3M
- ◆ Q3 2018 included collaboration milestones from Ipsen of \$41.9M



A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.

# Cash and Guidance

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## Cash at December 28, 2018: \$851.6M\*

- As compared to \$457.2M at December 31, 2017
- Exelixis free of debt obligations, with considerable cash to fund future opportunities

## 2019 Financial Guidance

- COGS: 4 - 5% of net product revenue
- R&D Expenses: \$285M - \$315M, which includes \$20M in non-cash stock-based compensation
- SG&A Expenses: \$220M - \$240M, which includes \$35M in non-cash stock-based compensation
- Tax rate: 21 - 23%

*Starting in the first quarter 2019, we will begin reporting non-GAAP financial measures that exclude stock-based compensation expense from our financial results*

# Commercial Update

PJ Haley  
SVP, Commercial

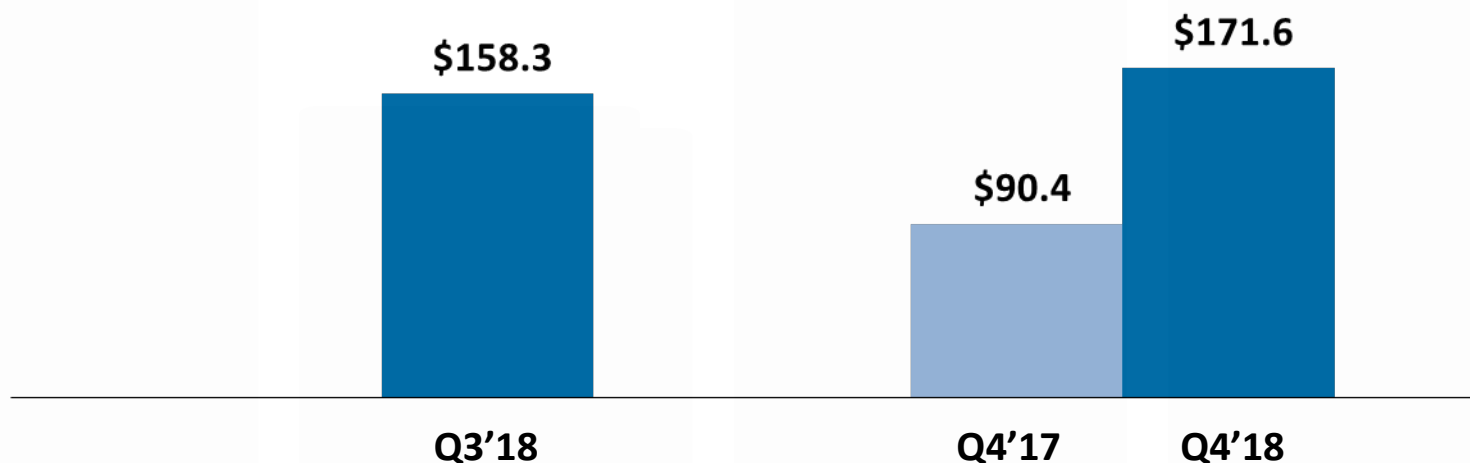


# Cabozantinib Franchise Q4'18 U.S. Net Revenue: \$176.2M

## CABOMETYX® U.S. Net Revenue (\$M)

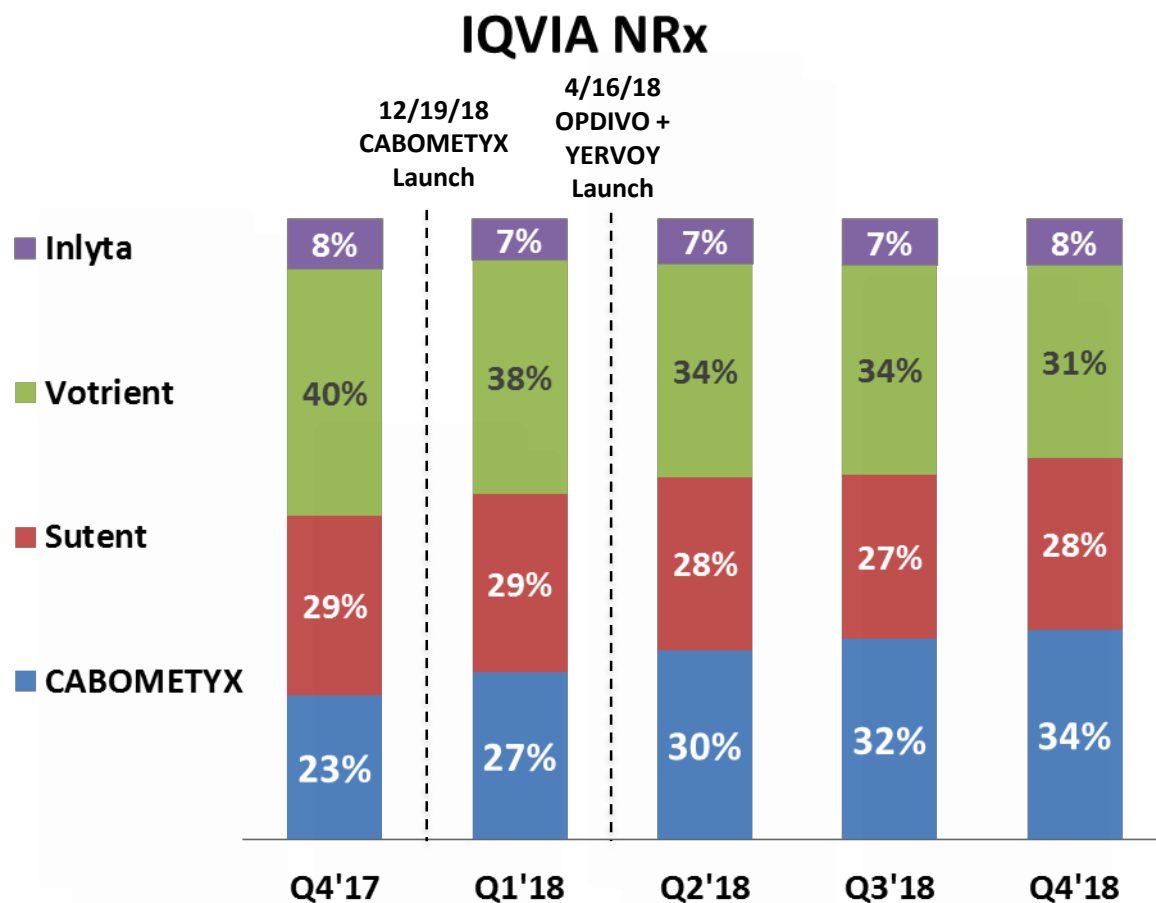
8% Growth Q/Q

90% Growth Y/Y



- Underlying product demand grew by 6% Q/Q and 66% Y/Y
- Prescriber base increased by 10% Q/Q and 68% Y/Y
- Broad utilization across academic/community, lines of therapy , and clinical risk categories

# Continued CABOMETYX IMS NRx TKI Market Share Growth



**CABOMETYX**  
**NOW #1 TKI** IN NEW PRESCRIPTIONS  
FOR aRCC<sup>a</sup>

National Comprehensive Cancer Network® (NCCN®)

**NCCN**  
PREFERRED

Cabozantinib (CABOMETYX) is  
**THE ONLY NCCN "PREFERRED" TKI** option  
for 1L intermediate/poor risk and 2L clear  
cell aRCC<sup>1</sup>

## Increased CABOMETYX demand in Q4'18

- 34% share in Q4'18
- + 2% NRx share increase over Q3'18
- +11% NRx share increase over Q4'17

Source: IQVIA, IQVIA National Prescription Audit™ 12/28/2018

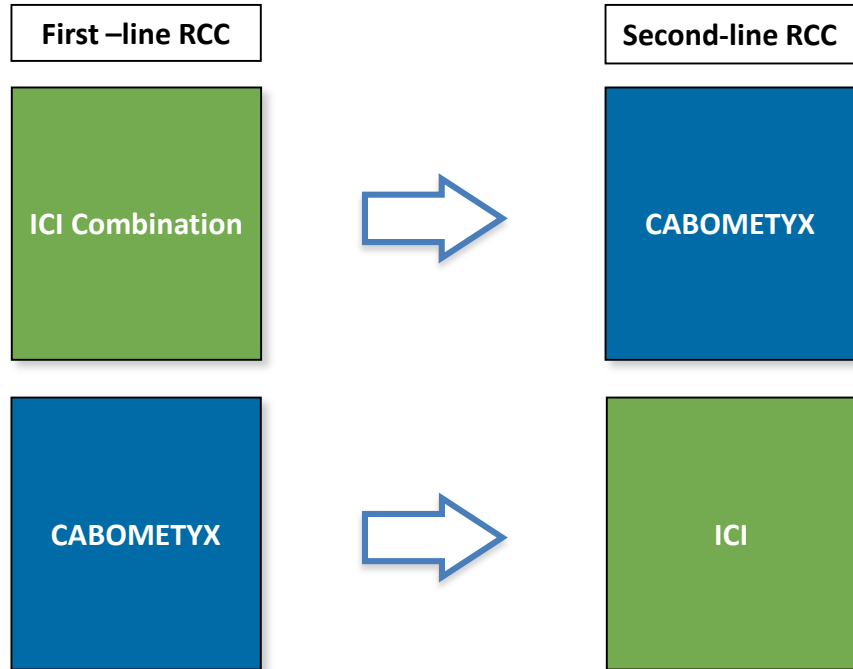
TKI market defined as Cabometyx, Inlyta, Sutent and Votrient, Rx data inclusive of all indications (not limited to RCC)

a. Based on IQVIA data as of October 2018, subject to change without notice.

1. The National Comprehensive Cancer Network makes no warranties of any kind whatsoever regarding their content, use or application and disclaims and responsibility for their application or use in any way.

# RCC Therapeutic Sequencing Consistent with Expectations

## RCC Therapeutic Sequencing

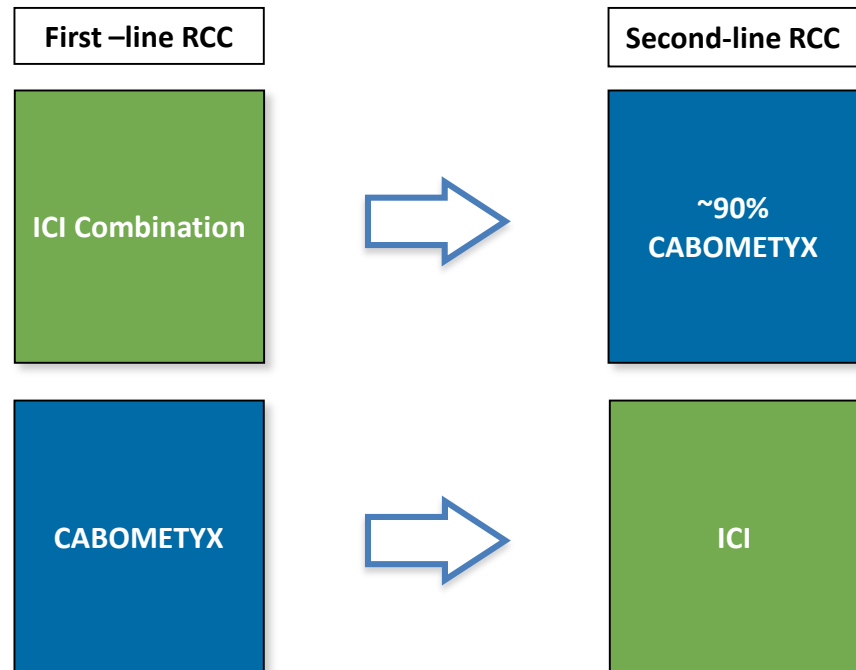


- Increasing numbers of 1L treated ipi/nivo patients are moving to 2L consistent with CM-214 PFS data
- Strong academic and community support for CABOMETYX as TKI of choice after ICI combination
- CABOMETYX market share grew in Q4 in 1st and 2nd lines of therapy\*

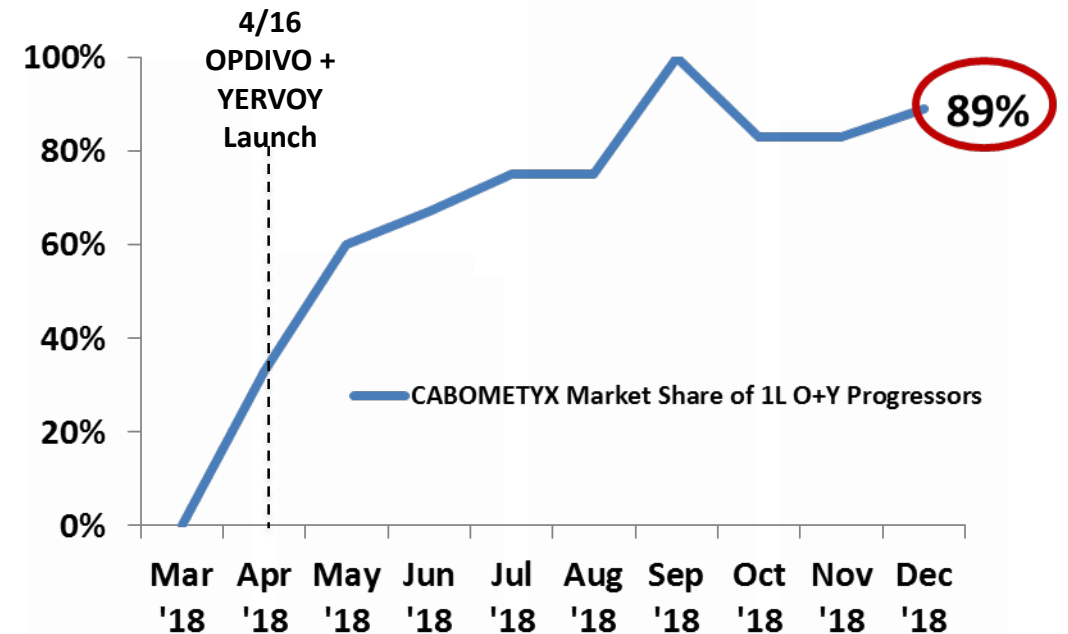
***CABOMETYX has strong momentum heading into 2019***

# CABOMETYX is Capturing ~90% of 1L Opdivo + Yervoy Progressors

## RCC Therapeutic Sequencing



## CABOMETYX Market Share of 1L Opdivo + Yervoy Progressors (R3M)



***2L CABOMETYX patients post-1L ICI treatment increasing***

# CABOMETYX is Now Approved in HCC



NOW APPROVED IN THE TREATMENT OF HCC<sup>1</sup>

## POWER FORWARD

WITH CABOMETYX<sup>®</sup> (cabozantinib)

Superior efficacy, now proven across 2 tumor types<sup>1\*</sup>

**SECOND-LINE HCC**  
CABOMETYX<sup>®</sup> (cabozantinib) is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

**FIRST- AND SECOND-LINE mRCC**  
CABOMETYX<sup>®</sup> (cabozantinib) is indicated for the treatment of patients with advanced renal cell carcinoma (mRCC).

HCC=International Metastatic Renal Cell Carcinoma Database Consortium; mRCC=Memorial Sloan Kettering Cancer Center

**IMPORTANT SAFETY INFORMATION**  
**WARNINGS AND PRECAUTIONS**  
**Hemorrhage:** Severe and fatal hemorrhages occurred with CABOMETYX. The incidence of Grade 3 to 5 hemorrhagic events was 5% in CABOMETYX patients. Discontinue CABOMETYX for Grade 3 or 4 hemorrhage. Do not administer CABOMETYX to patients who have a recent history of hemorrhage, including hemoptysis, hematemesis, or melena.

Please see additional important safety information throughout and full Prescribing Information.

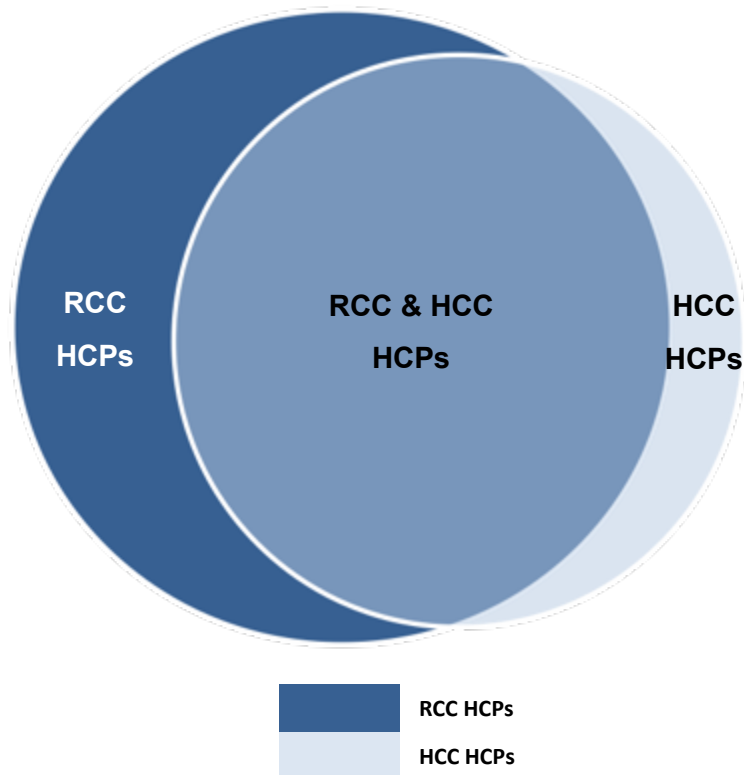
**CABOMETYX<sup>®</sup>**  
(cabozantinib) tablets

- Underserved market with expected increase in US drug-treated patients: 1L +37%, 2L +69%
- CABOMETYX has 3 FDA approvals in less than 3 years
- Promotion commenced immediately upon approval: January 14, 2019
- Timing of ASCO-GI conference (Jan. 17-19) provided excellent promotional opportunity

*HCC = hepatocellular carcinoma, FDA = U.S. Food & Drug Administration, 1L = first line, 2L = second line; FDA = U.S. Food & Drug Administration; ASCO-GI = American Society for Clinical Oncology's Gastrointestinal Conference*

# Significant Customer Overlap Leading to Launch Synergy

## RCC / HCC HCP Overlap & CABOMETYX HCC adoption



- HCC approval has increased account access and facilitated HCC discussions and incremental RCC discussions
- RCC & HCC prescribers overlap permits us to leverage CABOMETYX for RCC experience and should drive early adoption
- In addition to existing CABOMETYX prescribers, adoption being seen with new GI-focused prescribers

# CABOMETYX: The TKI of Choice in RCC

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## Strong Q4 business fundamentals

- Demand grew by 6% over Q3 and 66% over Q4 2017
- Prescriber base grew by 10% over Q3 and 68% over Q4 2017
- Broad utilization across academic and community settings, lines of therapy, and clinical risk groups

## CABOMETYX well positioned in RCC with strong momentum

- NCCN guidelines position CABOMETYX favorably: only preferred TKI in 1L\*/2L
- ~90% CABOMETYX use in the 2L after an ICI combination
- CABOMETYX grew in NRx market share in Q4 to 34% and is the #1 prescribed TKI NRx in RCC

## Early HCC launch execution and feedback encouraging

- HCC drug treated population expected to increase significantly by 2025
- Significant overlap of RCC and HCC market potential driven by community oncology
- HCC launch increasing account access and RCC customer interactions



Sources: Exelixis internal data, IMS data  
\*Intermediate / Poor Risk Patients

TKI = tyrosine kinase inhibitor, RCC = renal cell carcinoma; NRx = new prescriptions; HCC = hepatocellular carcinoma,  
1L = first line; 2L = second line, NCCN = National Comprehensive Cancer Network; ICI = immune checkpoint inhibitors

# Pipeline Update

Peter Lamb, Ph.D.  
EVP, Scientific Strategy & CSO



# Daiichi Sankyo Partnership for MINNEBRO™ (Esaxerenone)

*The third molecule from Exelixis drug discovery efforts to be approved*

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Identified during the prior research collaboration with DS, approved by Japanese Ministry of Health Labour and Welfare on January 8, 2019 to treat patients with hypertension

- DS has been solely responsible for MINNEBRO since November 2007

Exelixis will receive \$20M milestone payment upon first commercial sale of MINNEBRO in Japan

- Exelixis is eligible for additional commercialization milestones and low double-digit royalties on sales

~43M people in Japan, including 60% of men and 45% of women over 30, have hypertension<sup>1</sup>

In Q4 2017, DS began a phase 3 study in diabetic nephropathy (ESAX-DN), building on phase 2b work

<sup>1</sup>The Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2014). *Hypertens Research* 2014; 37: 253-392.

DS = Daiichi Sankyo

# Roche/Genentech Partnership for COTELLIC® (cobimetinib)

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## Two fully enrolled phase 3 pivotal trials in previously untreated melanoma

- IMspire150 TRILOGY: cobimetinib + vemurafenib + atezolizumab in BRAF mutation-positive, locally advanced or metastatic disease
- IMspire170: cobimetinib + atezolizumab in BRAF wild-type metastatic disease

## Potential regulatory filings later this year, if data are supportive

- Per Roche's FY 2018 results call on January 31, 2019

## Multiple Roche-sponsored earlier stage trials ongoing

- Studies in 13 different tumor types

# Progress Rebuilding the Pipeline

## Advancing discovery projects in new Alameda labs

- XL092, first compound to emerge from these efforts, now the subject of an active IND

## Business development group identifying oncology assets to feed into the pipeline

- 2018 deals with StemSynergy Therapeutics (CK1 $\alpha$  activator compounds) and Invenra (bispecific antibodies)
- Multiple additional opportunities under review



# Clinical Development Update

Gisela Schwab, M.D.

President, Product Development and Medical Affairs & CMO

# HCC: A New Indication for CABOMETYX

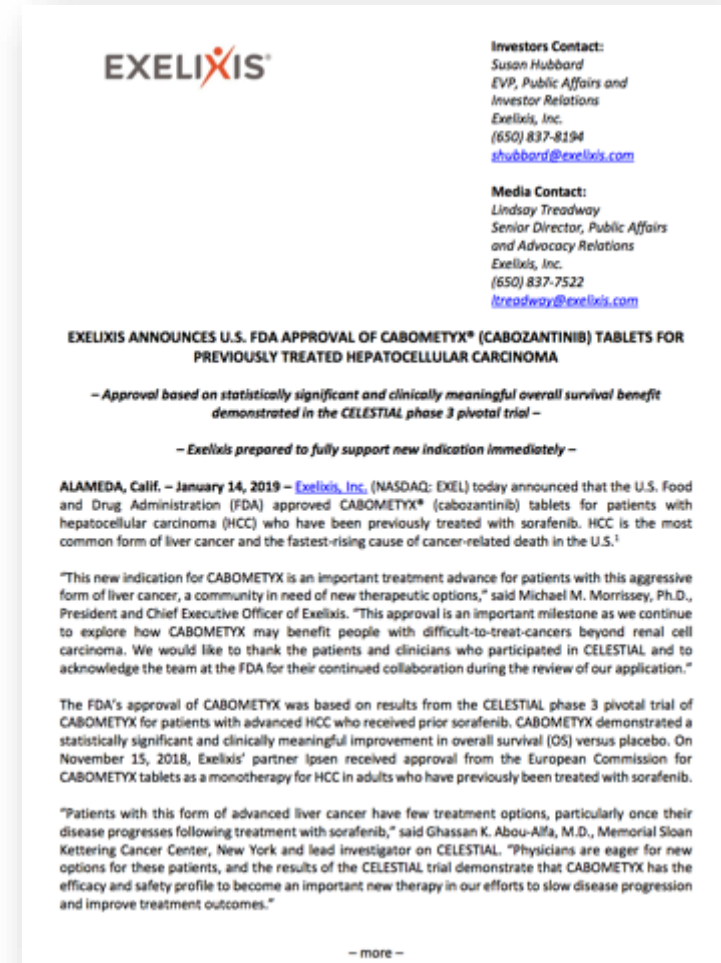
**November 15, 2018:**

**European Commission approval in adults who have received prior sorafenib**

- Followed positive CHMP opinion received in September 2018

**January 14, 2019:**

**U.S. FDA approval in patients with HCC who have been previously treated with sorafenib**



# Broad Development and Life Cycle Management Plan

## Single-Agent Cabozantinib

Differentiated thyroid cancer

## Cabozantinib Combined with ICIs

Multiple trials with different ICIs across a variety of indications are ongoing or planned as EXEL-sponsored trials (including 1L RCC and 1L HCC), IST or CTEP studies

## Cabozantinib Combined with Other Anti-Cancer Agents

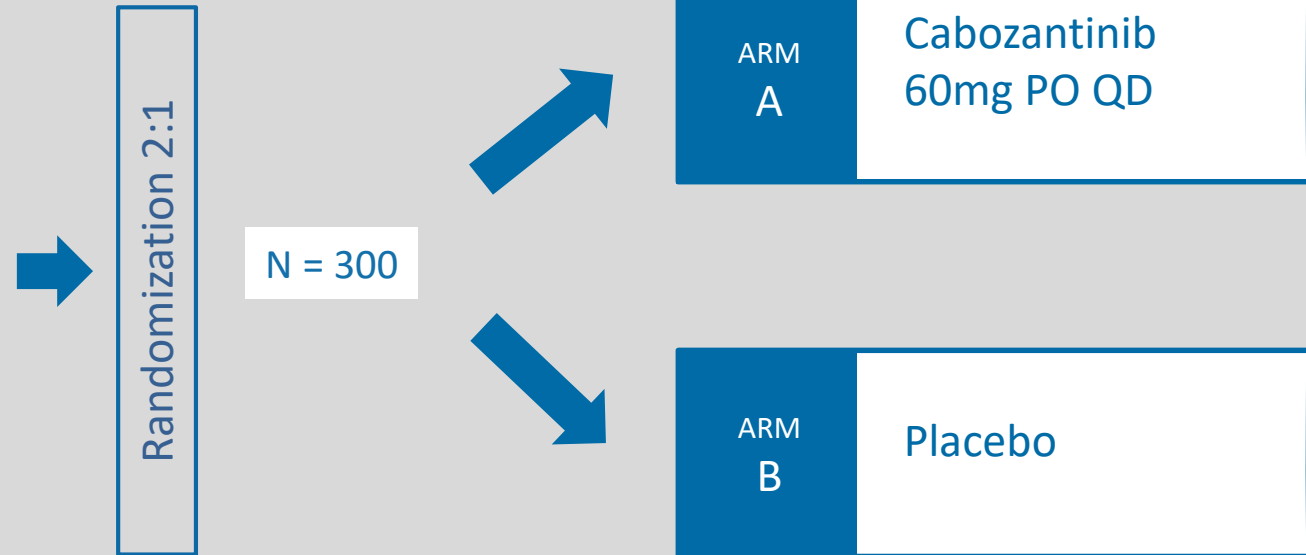
Advanced RCC (+ CB-839); numerous ISTs in a wide variety of tumor types evaluating cabozantinib in combination with targeted therapies and chemotherapeutic agents

# COSMIC-311 Enrolling: Phase 3 Pivotal Trial of Cabozantinib in DTC



## COSMIC-311 (Ph 3)

- A study of cabo vs placebo in patients with radioiodine-refractory DTC who have progressed after up to two prior VEGFR-targeted therapies
- Subjects must have measurable disease per RECIST 1.1



## Key Study Objectives

- **Co-Primary Endpoints:** PFS and ORR
- ORR endpoint will be analyzed among first 100 patients enrolled with appropriate follow-up



*DTC = Differentiated thyroid cancer; PFS = progression-free survival; ORR = objective response rate*

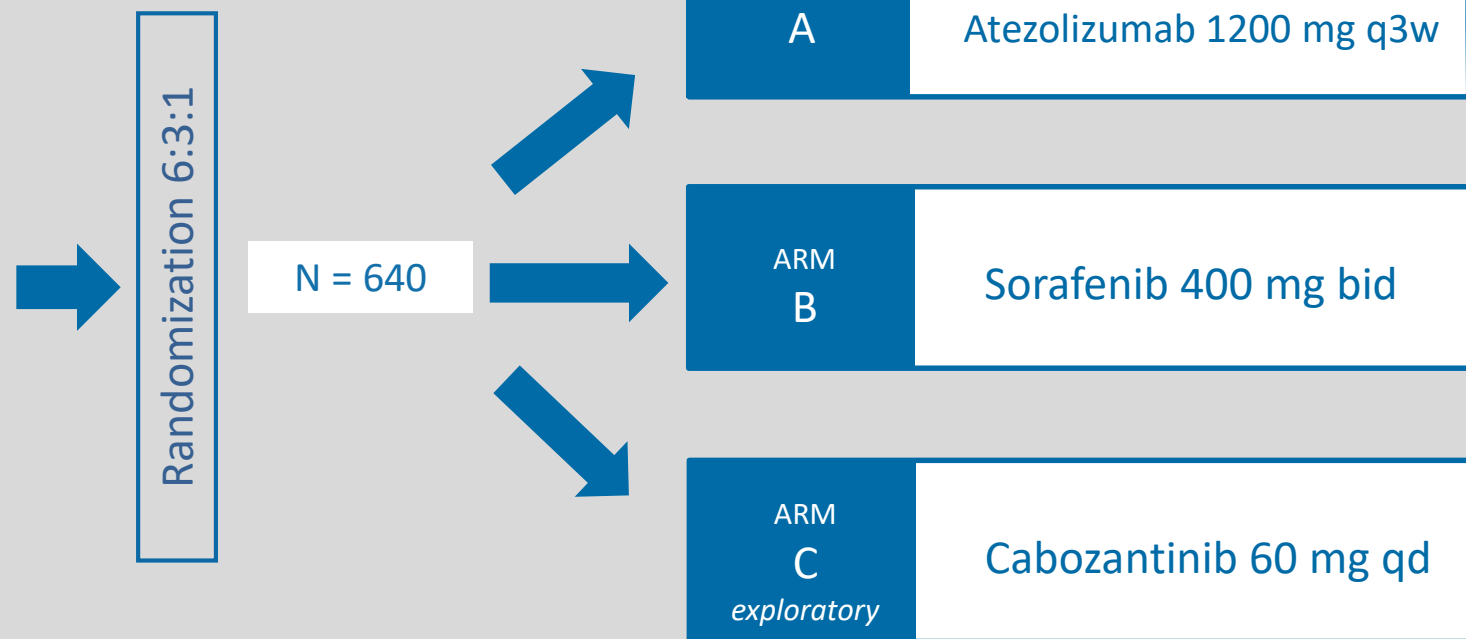
**Trial opened for  
enrollment  
October 2018**

# COSMIC-312 Enrolling: Phase 3 Pivotal Trial of Cabozantinib + Atezolizumab vs. Sorafenib in 1L Advanced HCC



## COSMIC-312 (Ph 3)

- Randomized, open-label study of cabo + atezo vs. sorafenib in previously untreated advanced HCC
- Target enrollment of 640 patients at up to 200 sites globally
- Exelixis-sponsored, with co-funding from Ipsen and atezolizumab provided by Genentech



## Key Study Objectives

- **Co-Primary Endpoints:** PFS by IRC; OS
- **Secondary:** ORR, safety

**Announced initiation on  
Dec. 5, 2018**



1L = first line; HCC = hepatocellular carcinoma; ; PFS = progression-free survival; IRC = independent radiology committee; OS = overall survival; ORR = objective response rate

# COSMIC-021 Enrolling: Phase 1b Trial of Cabozantinib + Atezolizumab in Multiple Tumors

*Exelixis-sponsored study in collaboration with Roche*

## Dose Escalation (RCC)

- Oral cabozantinib in combination with IV atezolizumab
- Recommended dose for expansion: cabozantinib 40 mg/day + atezolizumab 1200mg Q3W



*\* Cabozantinib active as a single agent in this histology*

## 18 Expansion Cohorts

|                                                                                     |                                                                         |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| UC* (n=30)<br>Prior platinum-chemotherapy                                           | UC* (n=30)<br>Cis-ineligible, treatment naïve                           |
| UC* (n=30)<br>Cis-eligible, treatment naïve                                         | UC* (n=30-80)<br>Prior ICI therapy                                      |
| ccRCC* (n=30)<br>Clear cell, treatment naïve                                        | CRPC* (n=30)<br>Prior enzalutamide or abiraterone                       |
| NSCLC* (n=30)<br>Treatment naïve                                                    | NSCLC* (n=30-80)<br>Prior ICI therapy                                   |
| NSCLC* (n=30)<br>Prior EGFR-targeting TKI                                           | nccRCC* (n=30)<br>Non-clear cell, treatment naïve                       |
| TNBC* (n=30)<br>Prior systemic therapy                                              | EOC* (n=30)<br>Platinum-resistant or refractory                         |
| EC* (n=30)<br>Prior systemic therapy                                                | HCC* (n=30)<br>Child-Pugh score of A; systemic therapy naïve            |
| GEJ* Carcinoma (n=30)<br>Prior platinum or fluoropyrimidine chemotherapy            | Colorectal adenocarcinoma (n=30)<br>Prior fluoropyrimidine chemotherapy |
| Head & neck cancer of squamous cell histology (n=30)<br>Prior platinum chemotherapy | DTC* (n=30)<br>Radio-refractory or iodine-131 ineligible                |

# Cabozantinib Plus ICIs

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## CheckMate 9ER pivotal trial making good progress enrolling patients globally

- Cabozantinib plus nivolumab, vs. sunitinib, in treatment-naïve RCC patients
- Co-funded by Exelixis, Ipsen, Takeda, and BMS (which is conducting the trial)
- Expecting results in 2H 2019, as discussed on BMS' recent earnings call

## Separate phase 3 pivotal trial of triplet regimen in start-up process

- Cabo/Nivo/Ipi vs. Nivo/Ipi in treatment-naïve RCC
- Ongoing phase 1b trial established safety, tolerability, and recommended dose

## Additional late-stage studies anticipated (e.g., bladder cancer and NSCLC)

# Introducing XL092

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*First internally-discovered Exelixis compound to enter the clinic following the company's reinitiation of drug discovery activities*

**Next-generation oral TKI targeting VEGF receptors and MET**

- Subject of active IND filed in late Q4 2018

**Soon-to-start phase 1 trial will include dose-escalation and expansion cohort stages**

**Should data warrant, will pursue both single-agent and combination approaches**

# Closing

Michael M. Morrissey, Ph.D.  
President and CEO



# 2018 Successes Provide the Platform for 2019

## BUILD

### ...on the strong CABOMETYX launch / status as TKI of choice for RCC

- Targeting entire RCC population independent of line of therapy, IMDC risk category, PD-L1 status
- Working towards a future where every eligible patient receives CABOMETYX in their 1L → 3L journey
- Research, feedback, experience suggest CABOMETYX is the TKI of choice for ICI-refractory patients
- Front-line ICI combinations could create 2L+ growth opportunity for years to come

## EXPAND

### ...cabozantinib's indications through new Ph 3 trials

- With COSMIC-311 in DTC and COSMIC-312 in HCC, second wave of pivotal trials underway
- Plans to initiate a Ph 3 trial evaluating Cabo/Nivo/Ipi vs Nivo/Ipi n 1L RCC are progressing
- COSMIC-021 (cabozantinib + atezolizumab) could inform potential third wave of studies

## ADVANCE

### ...next generation compounds, such as XL092

- Driven by our deep, fundamental knowledge of cabozantinib's pharmacology and its impact on tumor cells, the tumor vasculature and the immune-microenvironment
- Use growing cash position and financial depth for strategic transactions, licensing or acquiring compelling assets that are valued appropriately

# Exelixis Has Never Been Stronger: 25 Years, Resilient Together

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Treating and  
Defeating Cancer

EXELIXIS®



# Appendix



# GAAP to Non-GAAP Reconciliation: Net Income and Earnings Per Share

(in millions, except for per share amounts)

|                                                                                         | Three Months Ended December 31, |           | Year Ended December 31, |            |
|-----------------------------------------------------------------------------------------|---------------------------------|-----------|-------------------------|------------|
|                                                                                         | 2018                            | 2017      | 2018                    | 2017       |
| GAAP net income                                                                         | \$ 360,089                      | \$ 38,489 | \$ 690,070              | \$ 154,227 |
| Adjustment:                                                                             |                                 |           |                         |            |
| Income tax benefit resulting from the release of the valuation allowance <sup>(1)</sup> | (244,111)                       | —         | (244,111)               | —          |
| Non-GAAP net income                                                                     | \$ 115,978                      | \$ 38,489 | \$ 445,959              | \$ 154,227 |
| GAAP net income per share, basic                                                        | \$ 1.20                         | \$ 0.13   | \$ 2.32                 | \$ 0.52    |
| GAAP net income per share, diluted                                                      | \$ 1.15                         | \$ 0.12   | \$ 2.21                 | \$ 0.49    |
| Non-GAAP net income per share, basic                                                    | \$ 0.39                         | \$ 0.13   | \$ 1.50                 | \$ 0.52    |
| Non-GAAP net income per share, diluted                                                  | \$ 0.37                         | \$ 0.12   | \$ 1.43                 | \$ 0.49    |
| Shares used in computing net income per share, basic                                    | 299,409                         | 296,021   | 297,892                 | 293,588    |
| Shares used in computing net income per share, diluted                                  | 312,443                         | 313,342   | 312,803                 | 312,003    |

(1) Represents the non-cash income tax benefit related to the release of substantially all of the valuation allowance against the company's deferred tax assets on December 31, 2018.

## Use of Non-GAAP Measures:

The company believes that the presentation of non-GAAP measures is useful to investors because it excludes a non-cash tax benefit that resulted from the release of substantially all of the valuation allowance against the company's deferred tax assets. Management believes that presentation of operating results that excludes this item provides useful supplemental information to investors and facilitates the analysis of the company's core operating results and comparison of operating results across reporting periods. Management also believes that this supplemental non-GAAP information is useful to investors in analyzing and assessing the company's past and future operating performance. The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand the company's business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this presentation.

# Question and Answer Session



# Fourth Quarter and Full Year 2018 Financial Results

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Exelixis, Inc.  
NASDAQ: EXEL

Tuesday, February 12, 2019

