

# Second Quarter 2018 Financial Results

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Exelixis, Inc.  
NASDAQ: EXEL

Wednesday, August 1, 2018

# Forward-Looking Statements

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This presentation, including any oral presentation accompanying it, contains forward-looking statements, including, without limitation, statements related to: Exelixis' mission to help patients with cancer recover stronger and live longer; Exelixis' continued financial performance, including the growth of revenues and management of expenses to generate free cash to reinvest in the business; Exelixis' 2018 financial guidance for operating expenses; Exelixis' goal of CABOMETYX becoming the TKI of choice in the treatment of RCC; the commercial opportunity for cabozantinib as a treatment for patients with HCC; Exelixis' belief that the growth of CABOMETYX will be driven by approval in potential future indications; the potential future development of cabozantinib in combination with nivolumab or with nivolumab and ipilimumab in 1L advanced HCC; Exelixis' plan to enroll patients in the additional cohorts under the ongoing phase 1b trial evaluating cabozantinib and atezolizumab in the second half of 2018; Exelixis' plan to start additional pivotal trials with cabozantinib in 2018 and 2019, including DTC, bladder cancer, HCC and NSCLC as potential indications, and the opportunity for Ipsen and Takeda to participate under their respective agreements; Exelixis' plan to share study details as they progress towards initiation at the appropriate time; Exelixis' plans to give cabozantinib presentations at the ESMO 2018 Congress on October 19-23, including the first data presentation from the dose escalation phase of COSMIC-021, subgroup analyses of CELESTIAL, the phase 3 pivotal trial evaluating cabozantinib in patients with previously treated HCC, and updates of other investigator-sponsored trials; and Exelixis' belief that its strong performance in the first half of 2018 provides a strong foundation for future trials and opportunities to rebuild the pipeline. These statements are based on Exelixis' current expectations, assumptions, estimates and projections about its business and its industry and involve known and unknown risks, uncertainties and other factors that may cause results, timing, levels of activity, performance or achievements to be materially different from any actual results. Words such as "mission," "continued," "focused," "potential," "guidance," "towards," "goal," "future," "planned," "will," "opportunities," or the negative of such terms or other similar expressions, identify forward-looking statements. In addition, statements that refer to expectations, projections or characterizations of future events or their timing are forward-looking statements. Factors that might cause such a difference include, without limitation: the degree of market acceptance of CABOMETYX, COMETRIQ and COTELLIC and the availability of sufficient coverage and adequate reimbursement for these products; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; risks related to the potential failure of cabozantinib and cobimetinib, both alone and in combination with other therapies, to demonstrate safety and efficacy in clinical testing; Exelixis' dependence on its relationships with its collaboration partners, including, the level of their investment in the resources necessary to successfully commercialize partnered compounds in the territories where they are approved; Exelixis' ability and the ability of its collaborators to conduct clinical trials of cabozantinib and cobimetinib, both alone and in combination with other therapies, sufficient to achieve a positive completion; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; the availability of data at the referenced times; Exelixis' dependence on third-party vendors for the development, 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 August 1, 2018, and in Exelixis' future filings with the SEC. The forward-looking statements made in this presentation, including any oral presentation accompanying it, speak only as of the date on which the statements are made. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

# Today's Agenda

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## Introduction

**Susan Hubbard**

EVP, Public Affairs and Investor Relations

## Overview

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

President and Chief Executive Officer

## Financial Results & Guidance

**Chris Senner**

EVP and CFO

## Commercial Update

**PJ Haley**

SVP, Commercial

## Cabozantinib Development Update

**Gisela Schwab, M.D.**

President, Product Development and Medical Affairs and CMO

## Q&A

All, joined by:

**Peter Lamb, Ph.D.**

EVP, Scientific Strategy and CSO



# Overview

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



# Second Quarter 2018 Highlights

## Significant Revenue Growth

Cabozantinib net franchise revenues of ~\$146M; total revenues of ~\$186M; diluted EPS of \$0.28

## Regulatory and Development Progress

2L HCC sNDA filing accepted by FDA (PDUFA date 1/14/19); starting up next wave of cabozantinib late-stage trials

## Continued Pipeline Replenishment

Building upon current collaborations in 2018 and beyond; working with early-stage, innovative biotechs in a low-risk financial manner



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



# Significant Momentum in 2018

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## Reflection of our strong performance across all components of our business

- Focused on growing revenues and managing expenses to generate free cash to sustainably reinvest in the business
- Generated approximately \$1.2B in cabozantinib-related cash since early 2016

## Recently added to the S&P MidCap 400 Index

- Requires a company to have four consecutive profitable quarters, including most recent
- Recognizes companies that have passed many early-stage challenges, but still have potential for significant growth
- One of only two biotechnology companies currently in the index

# Financial Update

Chris Senner  
EVP and CFO



# Financial Highlights: Q2 2018

(in millions, except for per share amounts)

	<u>Q2' 17</u>	<u>Q1' 18 *</u>	<u>Q2' 18</u>	<u>YoY Delta</u>	<u>QoQ Delta</u>
<b>Total revenues</b>	<b>\$99.0 M</b>	<b>\$213.7 M</b>	<b>\$186.1 M</b>	<b>+88%</b>	<b>-13%</b>
<b>Cost of goods sold</b>	<b>\$3.0 M</b>	<b>\$5.6 M</b>	<b>\$6.0 M</b>	<b>+99%</b>	<b>+6%</b>
<b>R&amp;D expenses</b>	<b>\$28.2 M</b>	<b>\$37.8 M</b>	<b>\$42.5 M</b>	<b>+51%</b>	<b>+13%</b>
<b>SG&amp;A expenses</b>	<b>\$40.7 M</b>	<b>\$54.0 M</b>	<b>\$51.9 M</b>	<b>+27%</b>	<b>-4%</b>
<b>Total operating expenses</b>	<b>\$71.9 M</b>	<b>\$97.4 M</b>	<b>\$100.3 M</b>	<b>+40%</b>	<b>+3%</b>
<b>Other income (expense): net</b>	<b>\$(8.9) M</b>	<b>\$2.1 M</b>	<b>\$2.6 M</b>	<b>n/a</b>	<b>+27%</b>
<b>Provision for income taxes</b>	<b>\$(0.6) M</b>	<b>\$(2.5) M</b>	<b>\$(0.9) M</b>	<b>n/a</b>	<b>n/a</b>
<b>Net income **</b>	<b>\$17.7 M</b>	<b>\$115.9 M</b>	<b>\$87.5 M</b>	<b>+396%</b>	<b>-24%</b>
<b>Net income per share, diluted</b>	<b>\$0.06</b>	<b>\$0.37 †</b>	<b>\$0.28 §</b>	<b>+394%</b>	<b>-24%</b>
<b>Ending cash and investments ***</b>	<b>\$380.3 M</b>	<b>\$525.6 M</b>	<b>\$595.9 M</b>	<b>+57%</b>	<b>+13%</b>

\* Q1 2018 financial results as reported in our quarterly report on Form 10-Q filed with the 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 US Profit Share agreement with Roche. There was no impact to Net Income or EPS.

\*\* Amounts may not sum to total due to rounding

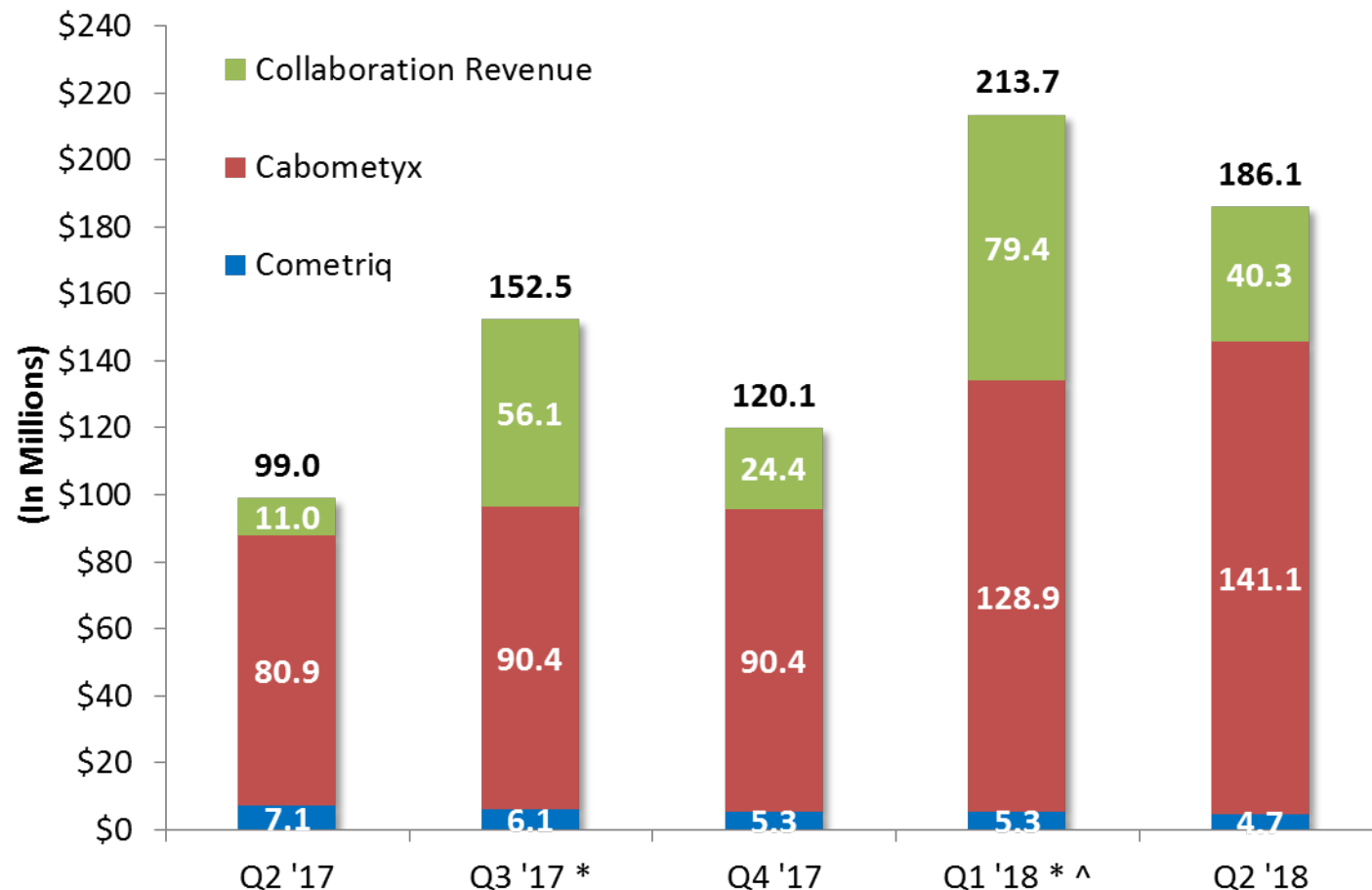
\*\*\* Includes cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments.

† Q1'18 net income per share, basic, is \$0.39  
§ Q2'18 net income per share, basic, is \$0.29



# Q2 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 in our quarterly report on Form 10-Q filed with the 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 US Profit Share agreement with Roche. There was no impact to Net Income or EPS.

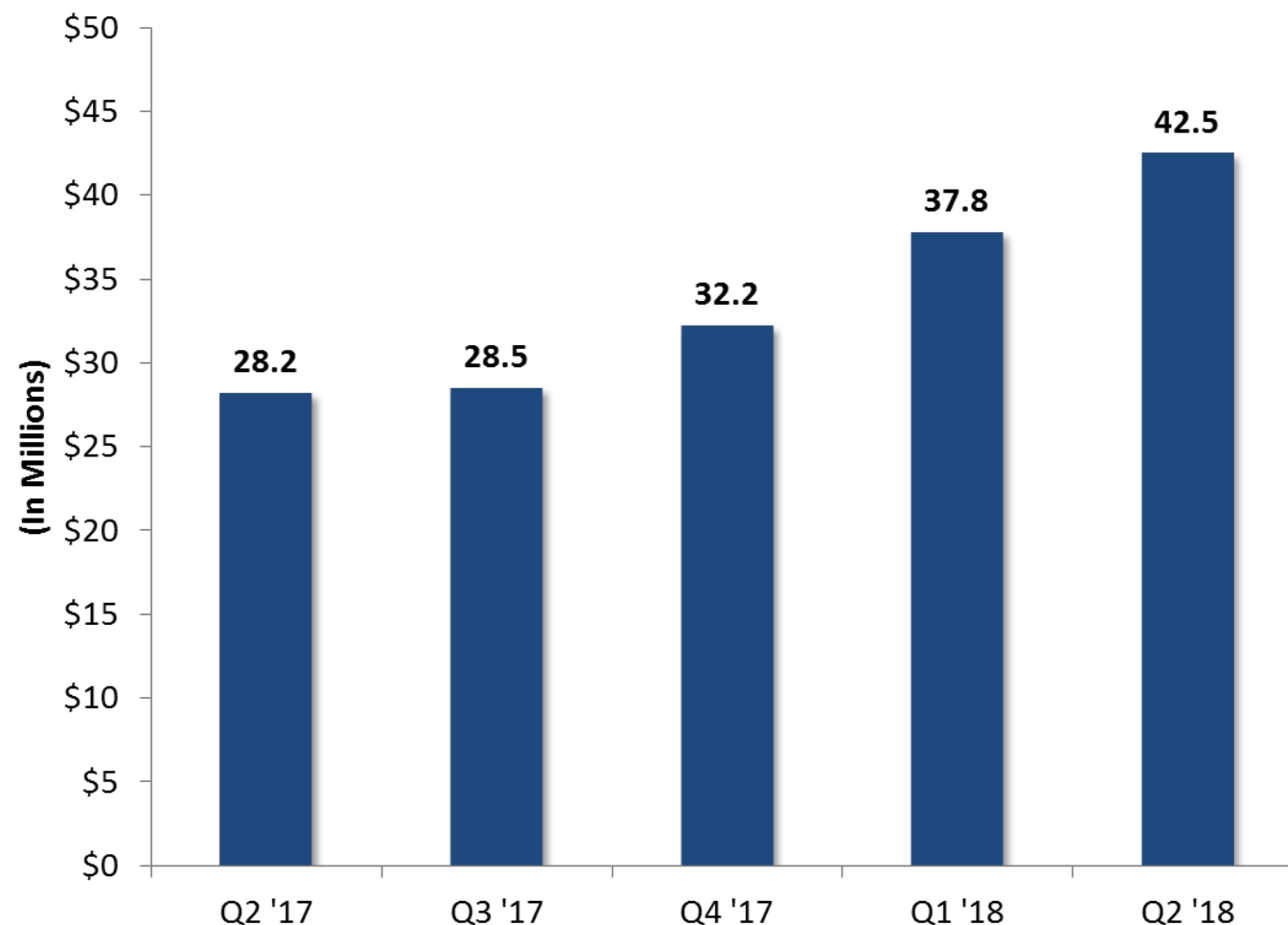


## Q2 2018 Notes

- ◆ Total revenues of \$186.1M
- ◆ \$145.8M in net product revenues, including \$141.1M in CABOMETYX and \$4.7M in COMETRIQ net product revenues
  - ❖ CABOMETYX product revenue higher in Q2 vs. Q1 due primarily to higher patient demand partially offset by a decrease in trade inventory
- ◆ Collaboration Revenue for Q2 2018 include:
  - ❖ \$25.0M milestone from Ipsen
  - ❖ \$6.9M in R&D reimbursements and amortization of upfront payments from Ipsen and Takeda
  - ❖ \$5.7M in Net Royalties from Ipsen and Genentech for Ex-US sales
  - ❖ \$2.7M in Cotellic US Profit Share

# Q2 2018 R&D Expense

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

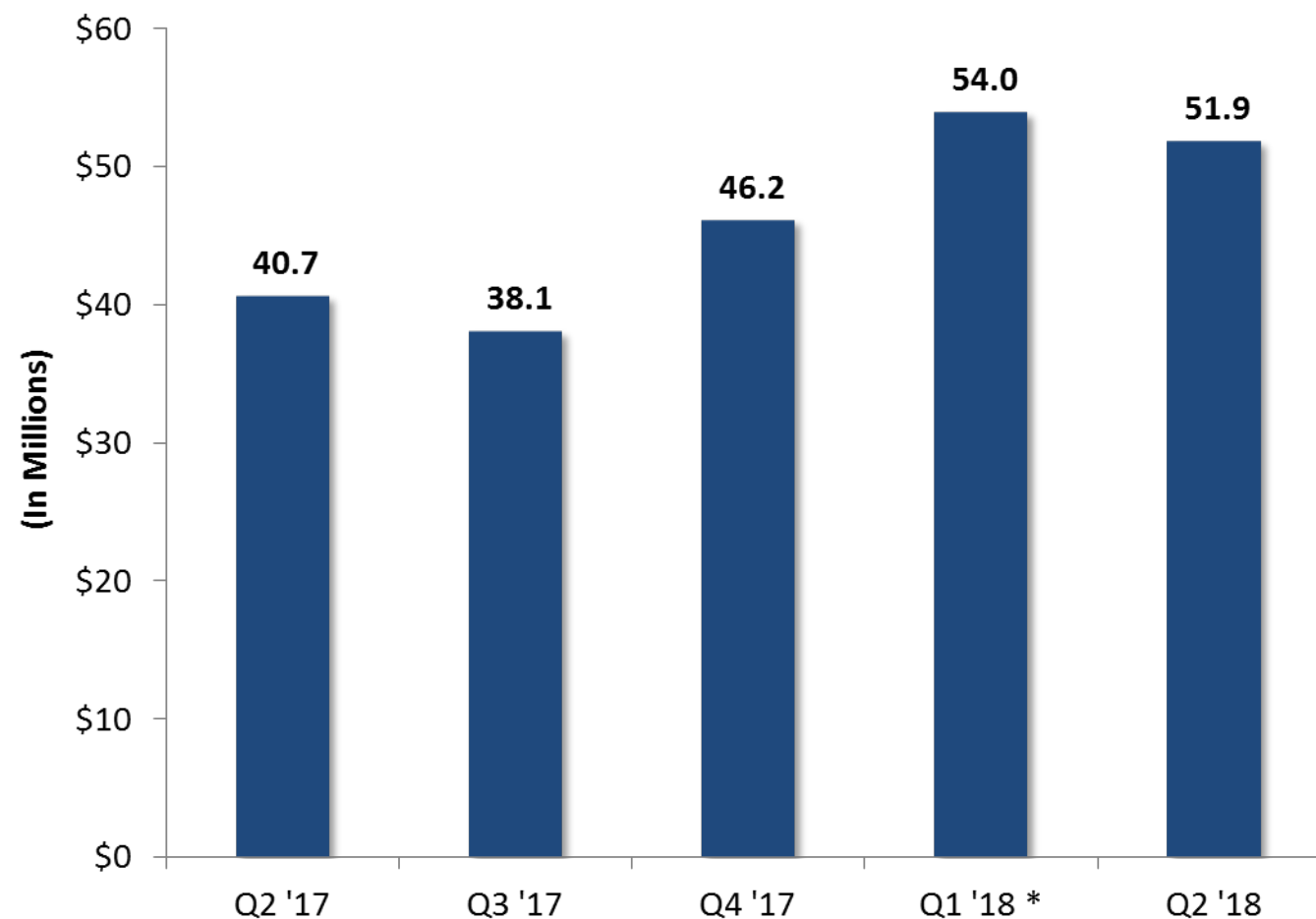


## Q2 2018 Notes

- ◆ R&D expenses of \$42.5M
- ◆ Increase in R&D expenses vs. Q1 2018 primarily a result of our collaboration and in-licensing agreement with Invenra, Inc. and increases in consulting, clinical trial and personnel expenses

# Q2 2018 SG&A Expense

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

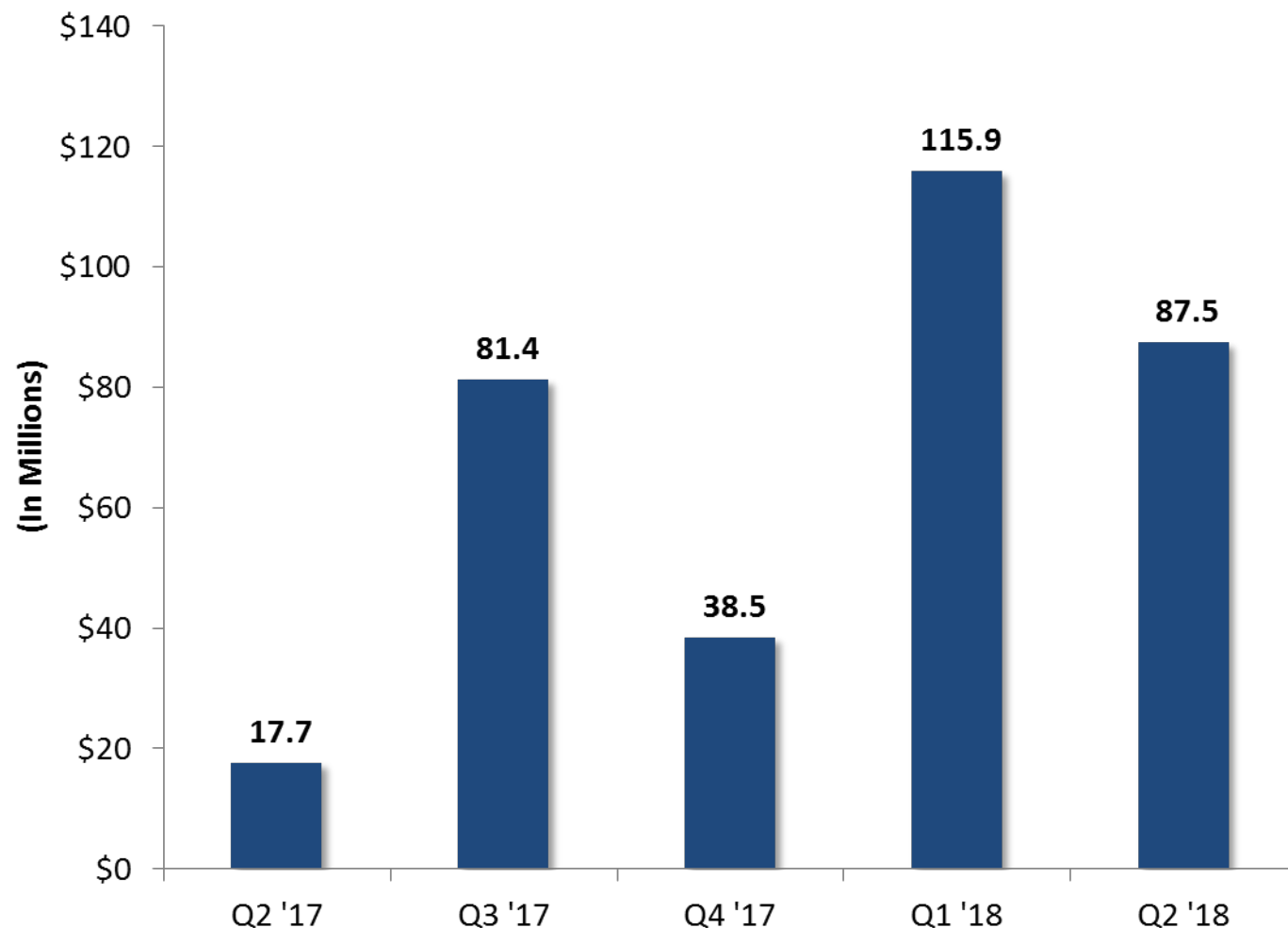


## Q2 2018 Notes

- ◆ SG&A expenses of \$51.9M
- ◆ Decrease in SG&A expenses vs. Q1 2018 is a result of decrease in corporate giving partially offset by increases in outside services expenses

# Q2 2018 Net Income

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

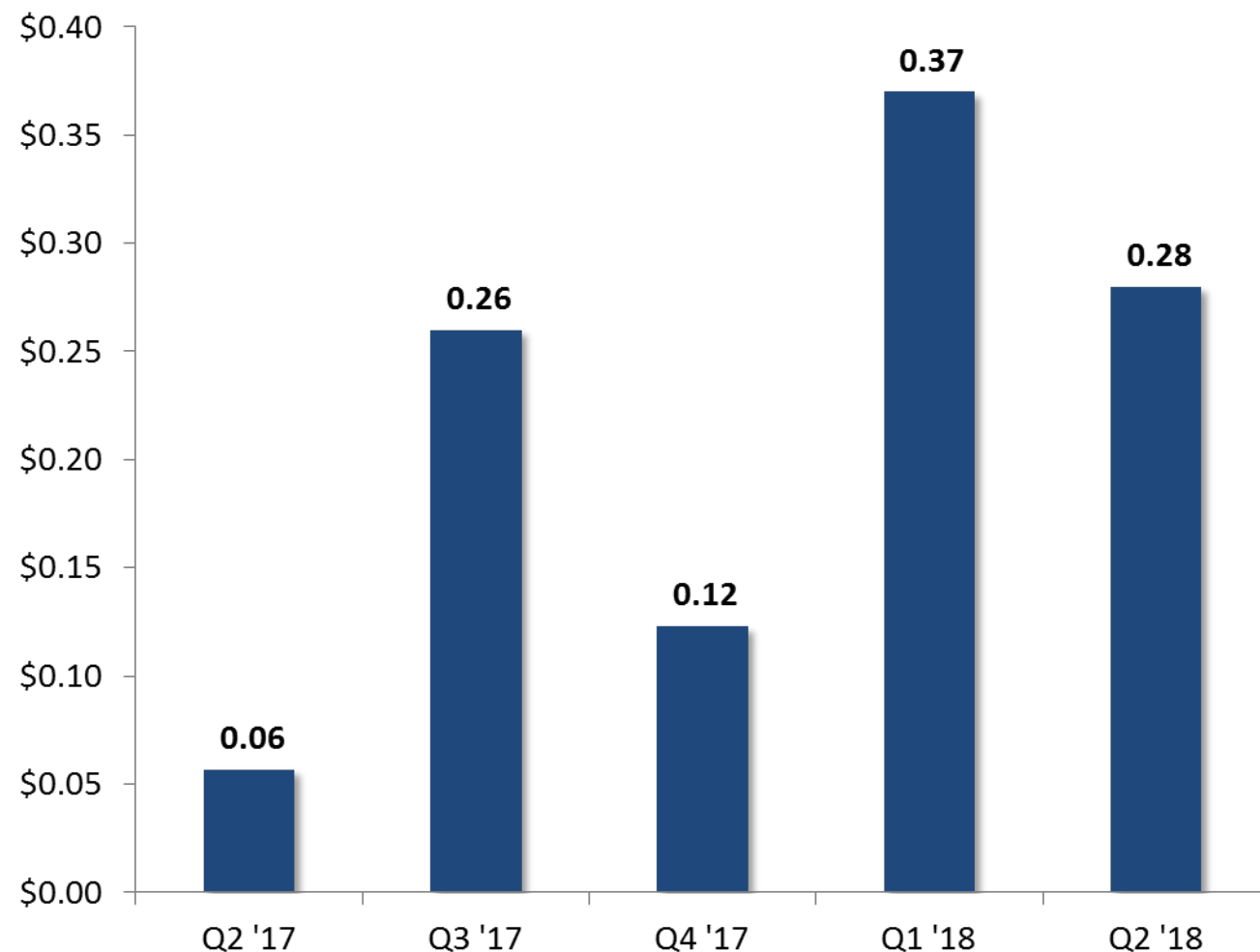


## Q2 2018 Notes

- ◆ Net Income of \$87.5M
- ◆ Decrease in Net Income vs. Q1 2018 driven by lower collaboration revenue, partially offset by higher CABOMETYX Product Revenue
- ◆ Q2 2018 included a collaboration milestone from Ipsen of \$25.0M
- ◆ Q1 2018 included collaboration milestones from Ipsen (of \$45.8M) and Daiichi Sankyo (of \$20.0M)

# Q2 2018 Earnings Per Share, Diluted

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



## Q2 2018 Notes

- ◆ Diluted EPS of \$0.28
- ◆ Decrease in Diluted EPS vs. Q1 2018 driven by lower collaboration revenue, partially offset by higher CABOMETYX Product Revenue
- ◆ Q2 2018 included a collaboration milestone from Ipsen of \$25.0M
- ◆ Q1 2018 included collaboration milestones from Ipsen (of \$45.8M) and Daiichi Sankyo (of \$20.0M)

# Cash and Operating Expense Guidance

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**Cash at June 30, 2018: \$595.9M\***

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

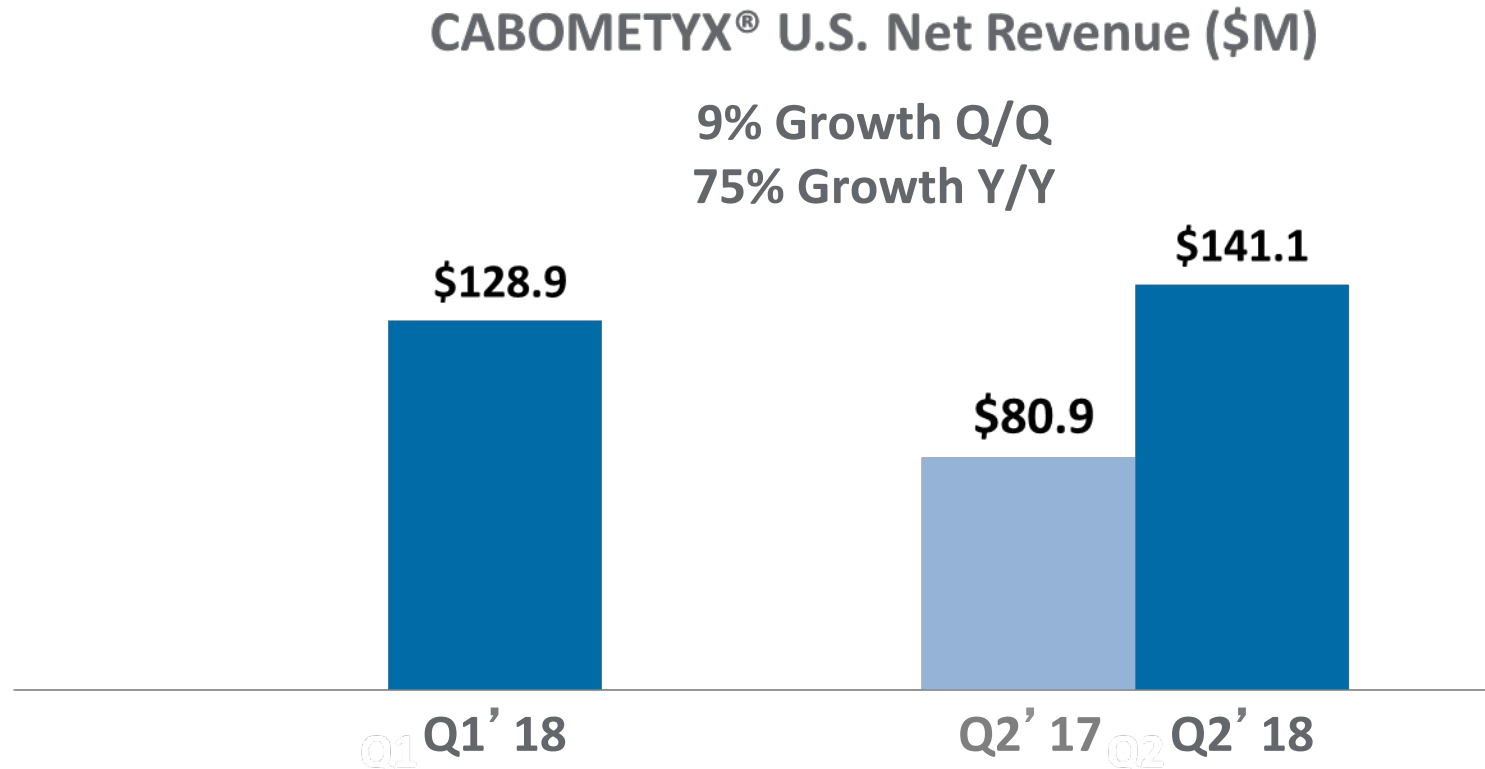
**Maintaining 2018 financial guidance : \$430-460M in operating expenses, which includes \$50M in non-cash items primarily related to share-based compensation**

# Commercial Update

PJ Haley  
SVP, Commercial



# Cabozantinib Franchise Q2 Net Revenue: \$145.8M



- Underlying product demand grew by ~16% Q/Q
- Strong growth driven by academic and community segments



# Q2 2018 CABOMETYX Business

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Expanded RCC indication enables growth in eligible patients and treating physicians

**CABOMETYX Q2' 18 net revenue = \$141.1M**

- Net revenue grew by 9% Q/Q
- Underlying product demand grew by ~16% Q/Q

**Launch metrics and physician feedback are positive**

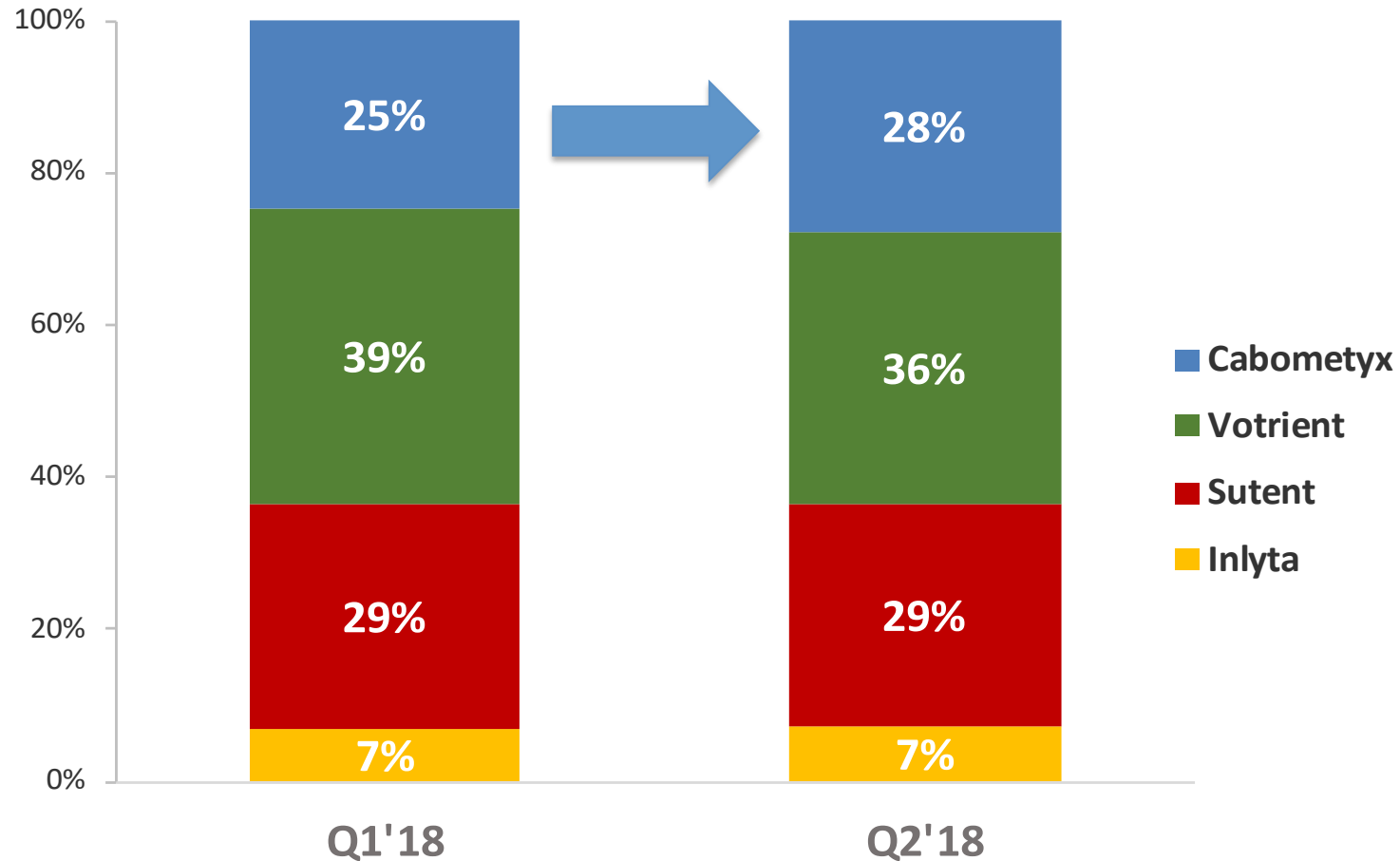
- Prescriber base increased by ~14%
- Product volume growth from both community and academic segments
- Utilization across clinical risk categories

**Increased new and continuing patient share in RCC TKI space**

- Significant progress towards goal of becoming the TKI of choice in RCC

# RCC TKI IMS Prescription Trends

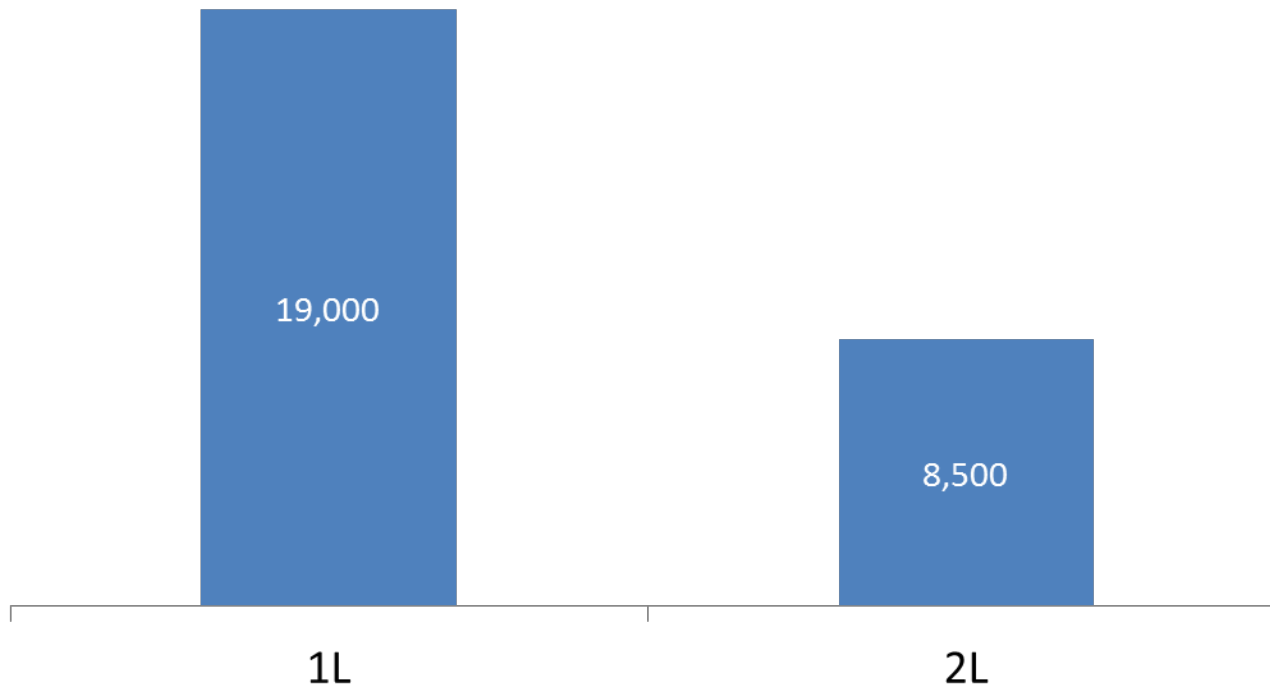
RCC TKI TRx Market Share



- CABOMETYX TRx outperformed RCC TKI Market in Q2 with 3% increase
- CABOMETYX TRx volume increased more than 13% in Q2 relative to Q1
- Growth of TRx driven by increased total patients on therapy

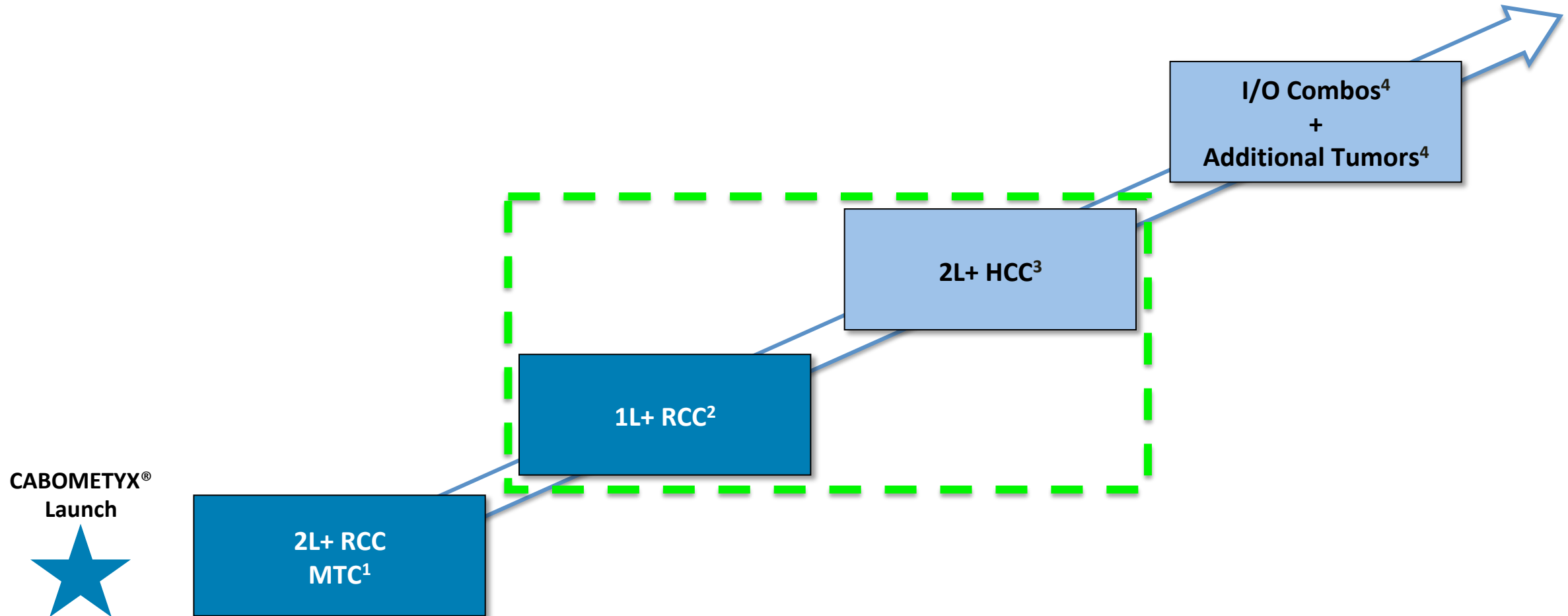
# Significant Unmet Need in HCC

U.S. Drug Treatable HCC Populations

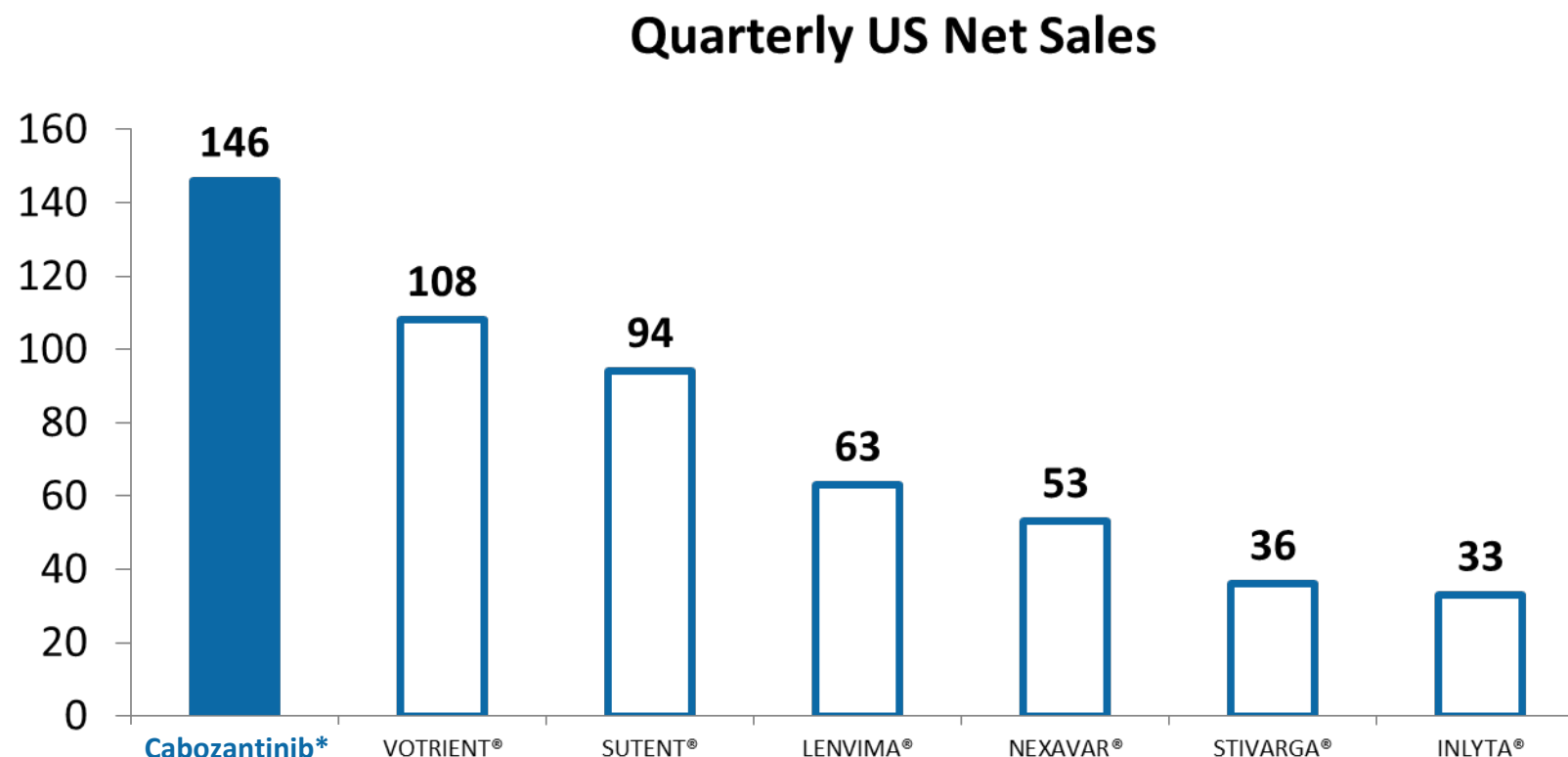


- In the U.S., there are ~40,000 diagnosed cases of liver cancer each year
- Approximately 29,000 deaths due to liver cancer each year in the U.S.
- Annual deaths due to HCC increased by 3% per year from 2008-2016
- Number of deaths attributed to HCC have doubled since 1999
- Underserved market with only one systemic therapy option until recently

# Growth Driven by Expansion of Indications



# Cabozantinib Established as the Leading VEGFR Targeting TKI



Sources: Q2' 18 Company earnings calls (includes all approved indications):

\*CABOMETYX® (RCC) / COMETRIQ® (MTC) – Q2' 18

VOTRIENT® (RCC, Soft Tissue Sarcoma) – Q2' 18

SUTENT® (GIST, RCC, pNET) – Q2' 18

LENVIMA® (DTC, RCC) – Americas Revenue Q2' 18

NEXAVAR® (HCC, RCC, DTC) – Q1' 18

STIVARGA® (CRC, GIST, HCC) – Q1' 18

INLYTA®(RCC) – Q2' 18

RCC = renal cell carcinoma, TKI = tyrosine kinase inhibitor

- Cabozantinib has exceeded comparable revenue of other leading VEGFR targeting TKIs
- Substantial near to medium term growth in both RCC and 2L HCC
- Establish Cabozantinib as the TKI of choice<sup>1</sup>

<sup>1</sup> For approved indications

# Cabozantinib Development Update

Gisela Schwab, M.D.

President, Product Development and Medical Affairs & CMO

# Recent Product Development Updates

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European Commission approved cabozantinib for the treatment of patients with previously untreated intermediate or poor risk RCC in May 2018 (Ipsen territory)

FDA accepted Exelixis' sNDA filing in previously treated HCC in March 2018

- Assigned PDUFA date of January 14, 2019

CELESTIAL data was published in *The New England Journal of Medicine* in July 2018

European Medicines Agency validated Ipsen' s EU label variation filing in previously treated HCC in March

RCC = renal cell carcinoma; sNDA = Supplemental New Drug Application; HCC = hepatocellular carcinoma; EU = European Union

# Progress Evaluating Cabozantinib with BMS Immune Checkpoint Inhibitors (ICIs)

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## Phase 2 study of cabozantinib+nivolumab and cabozantinib+nivolumab+ipilimumab in advanced HCC completed enrollment

- Evaluating preliminary safety and efficacy of the combinations as part of CheckMate 040 trial
- Primary endpoint of safety; secondary endpoints include ORR and PFS
- Important for future development, including in potential 1L applications

## Based on encouraging prior data, phase 3 CheckMate 9ER in previously untreated RCC is enrolling globally

- Cabozantinib+nivolumab vs. sunitinib
- Co-funded by Exelixis, Ipsen, Takeda, and BMS, which is conducting the study

## Separate phase 3 trial investigating cabozantinib +nivolumab+ipilimumab vs. nivolumab+ipilimumab in development

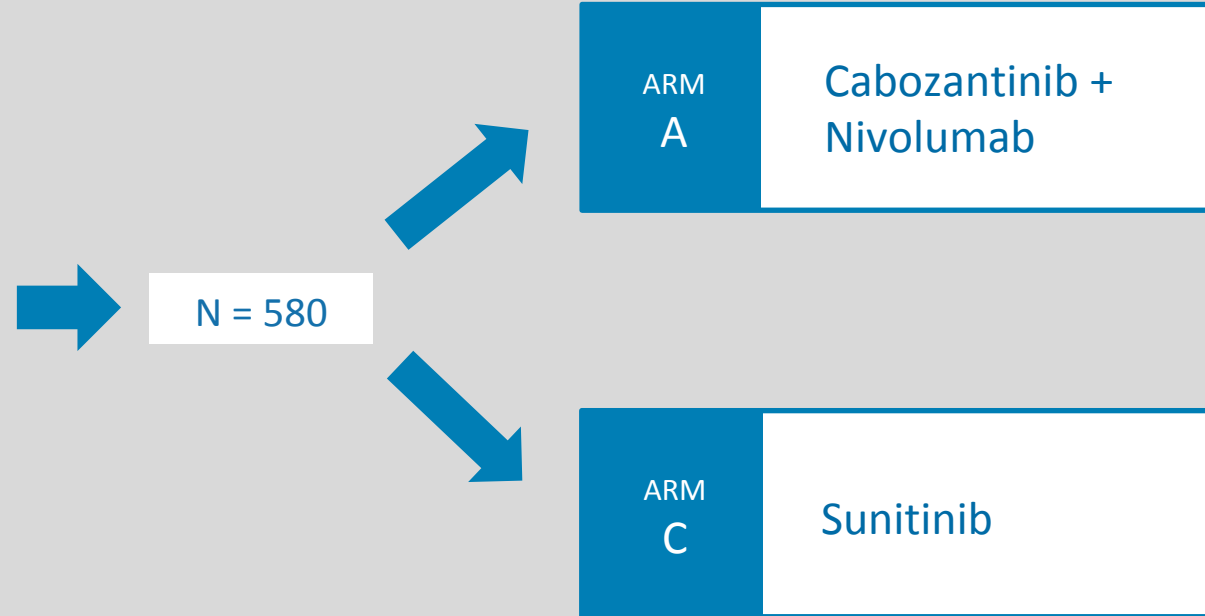
- Targeting the 1L RCC setting



# CheckMate 9ER: First IO Combination Trial Initiated Under Clinical Development Collaboration with BMS

## CheckMate 9ER (Ph 3)

- A study of cabozantinib+nivolumab vs. sunitinib in previously untreated advanced or metastatic RCC of all risk categories
- Requires histologically confirmed disease with a clear cell component
- Protocol amendment removed Arm B (cabo/nivo/ipi) based on results from CM-214



## Key Study Objectives

- **Primary:** PFS [assessed by blinded independent central review (BICR)]
- **Secondary:** OS, ORR, safety

First patient enrolled  
in July 2017

# Progress Evaluating Cabozantinib with BMS Immune Checkpoint Inhibitors (ICIs)

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**Separate phase 3 trial investigating cabozantinib+nivolumab+ ipilimumab vs. nivolumab+ipilimumab in development**

- Targeting the 1L RCC setting

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

*Exelixis-sponsored study under our clinical trial collaboration with Roche*

## Dose Escalation (RCC, UC)

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

**2017/2018 cohort – enrolling**

**June 2018 cohort – enrolling 2H' 18**

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

## Dose Expansion (Eight cohorts enrolling; 10 additional announced in June 2018 to begin enrolling soon)

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

# Other Clinical Development Updates

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## Additional pivotal trials with cabozantinib planned to start in 2018 and 2019

- Indications including DTC, bladder cancer, HCC, and NSCLC under discussion
- Ipsen and Takeda will each have the opportunity to participate under their respective agreements
- Will share the details of the studies as they progress towards initiation at the appropriate time

## Study concepts also advancing through NCI-CTEP and Investigator-Sponsored Trial program

- Phase 2 trials combining cabozantinib with ICIs moving forward in triple-negative breast, endometrial, and 2L NSCLC

## Phase 3 study in PNET and carcinoid now open and actively recruiting patients

## Cabozantinib presentations at the ESMO 2018 Congress (October 19-23, Munich)

- First data presentation from COSMIC-021 (dose escalation phase; cohort data to come later)
- Subgroup analyses of the CELESTIAL trial
- Other investigator-sponsored trial updates, real world observations, and more

# Closing

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



# A Strong First Half of 2018

**Solid performance  
in all aspects of the business**

**A foundation for future trials and new  
opportunities to rebuild the pipeline**



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

# Question and Answer Session



# Appendix





# Cobimetinib Development Program

COBIMETINIB PHASE 3 DEVELOPMENT ACTIVITIES‡		
Indication / Disease State	Combination Regimen	Status Update
Metastatic or Unresectable Locally Advanced Melanoma		
BRAF mutation-positive	+ vemurafenib	Approved in U.S., EU and other territories
First-line BRAF mutation-positive	+ atezolizumab + vemurafenib	Phase 3 (IMspire150)*, enrollment completed
First-line BRAF wild-type	+ atezolizumab	Phase 3 (IMspire170)*
Colorectal Cancer		
Third-line advanced or metastatic disease	+ atezolizumab	Per May 9th update, phase 3 (IMblaze370) trial did not meet its primary endpoint

‡ Cobimetinib is being evaluated in a broad development program consisting of more than 50 clinical trials by Genentech or through Genentech’s investigator sponsored trial program. The trials indicated in the above table are all sponsored by Genentech. For a complete list of trials, please visit <https://clinicaltrials.gov>.

\* Ongoing clinical trial.



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