

# Incyte Corporation

Q3 2017 Financial and Corporate Update

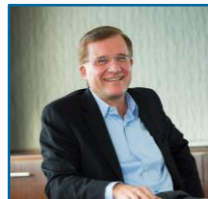
October 31, 2017

# Speakers



**Hervé Hoppenot**

Chief Executive Officer



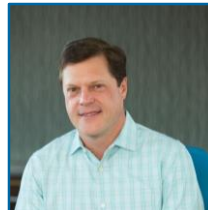
**David Gryska**

Chief Financial Officer



**Barry Flannelly**

General Manager, U.S.



**Reid Huber**

Chief Scientific Officer



**Steven Stein**

Chief Medical Officer



# Forward-looking Statements

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Except for the historical information set forth herein, the matters set forth in this presentation contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: our financial guidance for 2017; whether growth in sales and market share of, and demand for, Jakafi, will continue to grow; whether Jakafi will continue to be a revenue driver for us and enable the Company's development portfolio to lead to transformational growth; whether opportunities for further development of ruxolitinib in GVHD and ET will be successful; whether Jakafi will achieve our long-term net product revenue guidance in MF, PV and GVHD; whether baricitinib for RA will be approved in the U.S., whether and when a new clinical trial will be undertaken for baricitinib for RA in the U.S., whether and when the NDA for baricitinib for RA will be resubmitted to the FDA, whether baricitinib will ever be approved in the U.S. for any indication and whether development of baricitinib in other indications will be successful or will continue as currently planned, including for atopic dermatitis; whether we will receive any further milestones from Lilly in connection with baricitinib development; plans and expectations regarding our product pipeline and strategy (including without limitation plans and expectations relating to epacadostat, ruxolitinib, itacitinib, INCB50465 and INCB54828) - including timelines for advancing our drug candidates through clinical trials (including enrollment and commencement), whether certain trials will serve as the basis for registration, timelines for regulatory submissions and timelines for releasing trial data, the number of potential clinical trials, and whether any specific program will be successful - and plans and expectations regarding development activities of our collaboration partners (including without limitation collaboration development activities relating to capmatinib and baricitinib); whether and when any of our product candidates or those licensed to our collaborators will be approved for treatment in humans in any country in the world and, if approved, whether any such product candidate will contribute meaningfully to our revenue; whether the plans and expectations regarding the Company's pipeline over the next 12 months will occur as planned or drive potential value; the potential therapeutic and commercial value of our drug candidates; and whether Incyte will become a highly profitable biopharmaceutical company.

These forward-looking statements are based on our current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the efficacy or safety of our products; the acceptance of our products in the marketplace; market competition; further research and development; sales, marketing and distribution requirements; clinical trials, including pivotal trials, possibly being unsuccessful or insufficient to meet applicable regulatory standards for clinical advancement or approval or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA; other market, economic or strategic factors and technological advances; unanticipated delays; our ability to compete against parties with greater financial or other resources; our dependence on our relationships with our collaboration partners; greater than expected expenses; expenses relating to litigation or strategic activities; our ability to obtain additional capital when needed; obtaining and maintaining effective patent coverage for our products; and other risks detailed from time to time in our reports filed with the Securities and Exchange Commission, including our Form 10-Q for the quarter ended June 30, 2017, as amended. We disclaim any intent or obligation to update these forward-looking statements.





# Quarterly Review

**Hervé Hoppenot**

President & CEO



# Significant and Consistent Growth over the last Five Years

- **Four sources of revenue**

- Jakafi® (ruxolitinib) in the U.S.
- Iclusig® (ponatinib) in Europe
- Royalties from Jakavi® (ruxolitinib)
- Royalties from Olumiant® (baricitinib)

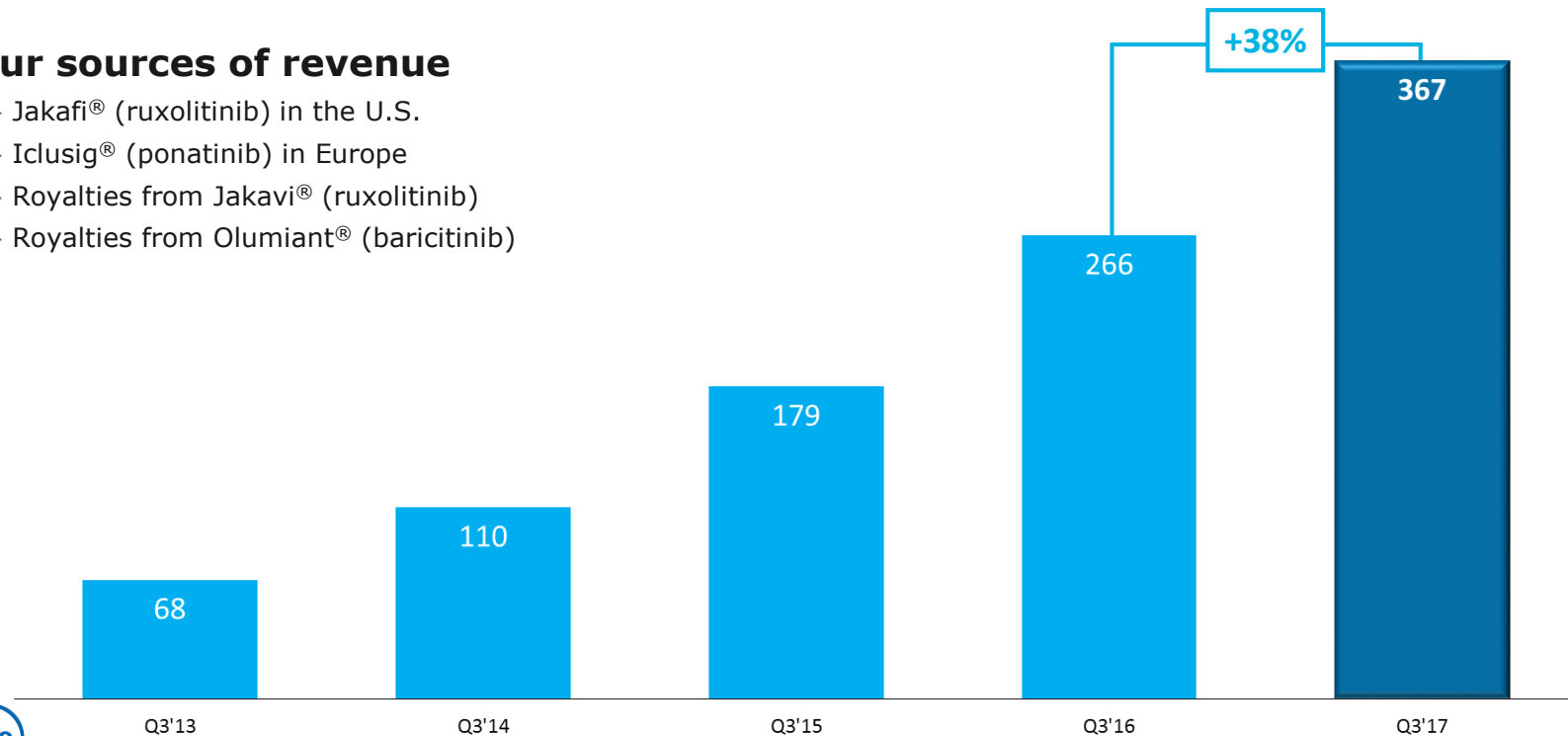


Chart shows product-related revenue in the third quarter of each year 2013 to 2017 (\$ million; sales of Jakafi® (ruxolitinib) in the U.S. and Iclusig® (ponatinib) in Europe, and royalties from ex-U.S. sales of Jakavi® (ruxolitinib) by Novartis and Olumiant® (baricitinib) by Lilly)

# Five Product Candidates in Late-Stage Development

**REACH**  
RESET

**GRAYITAS**

**fight**

**citadel**

**ECHO** 

ruxolitinib

JAK1/JAK2

Graft-versus-host disease<sup>1</sup>

Essential thrombocythemia

itacitinib

JAK1

Graft-versus-host disease<sup>2</sup>

INCB54828

FGFR1/2/3

Cholangiocarcinoma

Bladder cancer

INCB50465

PI3Kδ

DLBCL

Follicular lymphoma

Marginal zone lymphoma

Mantle cell lymphoma

epacadostat

IDO1

Melanoma

Incyte development portfolio includes earlier-stage clinical programs targeting BRD, PIM, LSD1, FGFR4, GITR, OX40, PD-1 and arginase



Late-stage development includes Phase 3 trials and Phase 1/2 trials being conducted in defined indications that have the potential to be registration-enabling

1. Studies are evaluating ruxolitinib in steroid-refractory GVHD patients
2. Studies are evaluating itacitinib in steroid-naïve GVHD patients

# Leadership Position in Immuno-Oncology

## Epacadostat combinations

### **Pembrolizumab**

- Melanoma
- Bladder, kidney, head & neck, NSCLC

### **Nivolumab**

- Head & neck, NSCLC

## Potential I/O combinations

**IDO1** (epacadostat)

**GITR** (INCAGN1876<sup>1</sup>)

**OX40** (INCAGN1949<sup>1</sup>)

**Arginase** (INCB01158<sup>2</sup>)

**JAK1** (itacitinib)

**BRD** (INCB57643)

**PI3K $\delta$**  (INCB50465)



1. Discovery alliance with Agenus
2. Development in collaboration with Calithera

# Leadership Position in Immuno-Oncology

Further reinforced with new collaborations

## Epacadostat combinations

### Pembrolizumab

- Melanoma
- Bladder, kidney, head & neck, NSCLC

### Nivolumab

- Head & neck, NSCLC

### Durvalumab

- NSCLC

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### PD-1 antagonist (MGA012<sup>3</sup>)

Exclusive worldwide commercial and development rights



1. Discovery alliance with Agenus
2. Development in collaboration with Calithera
3. Development in collaboration with MacroGenics

# Well Positioned to Accelerate Future Revenue Growth

- **Investments in innovation**

- Three discovery platforms
- 17 clinical development candidates

- **Five late-stage programs**

- Currently being evaluated across ten indications
- Ten pivotal trials running or planned for epacadostat

- **Preparing for multiple potential product launches**

- Operations in North America, Europe, and Japan





# Jakafi<sup>®</sup> Performance

**Barry Flannelly**

General Manager, U.S.



# Jakafi® Revenue Continues to Outperform Expectations

- **Excellent revenue growth**

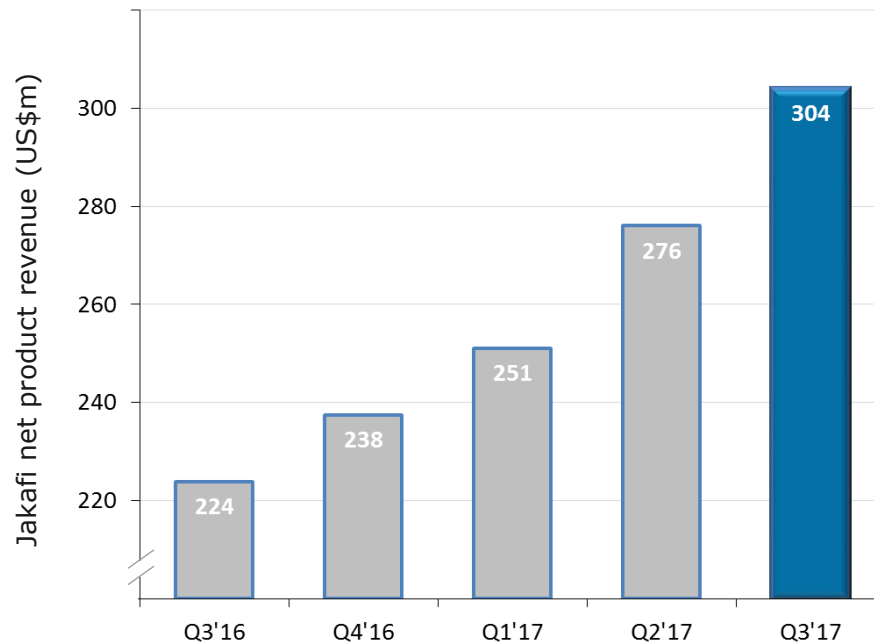
- 36% year-on-year
- 10% quarter-on-quarter

- **Robust prescription demand**

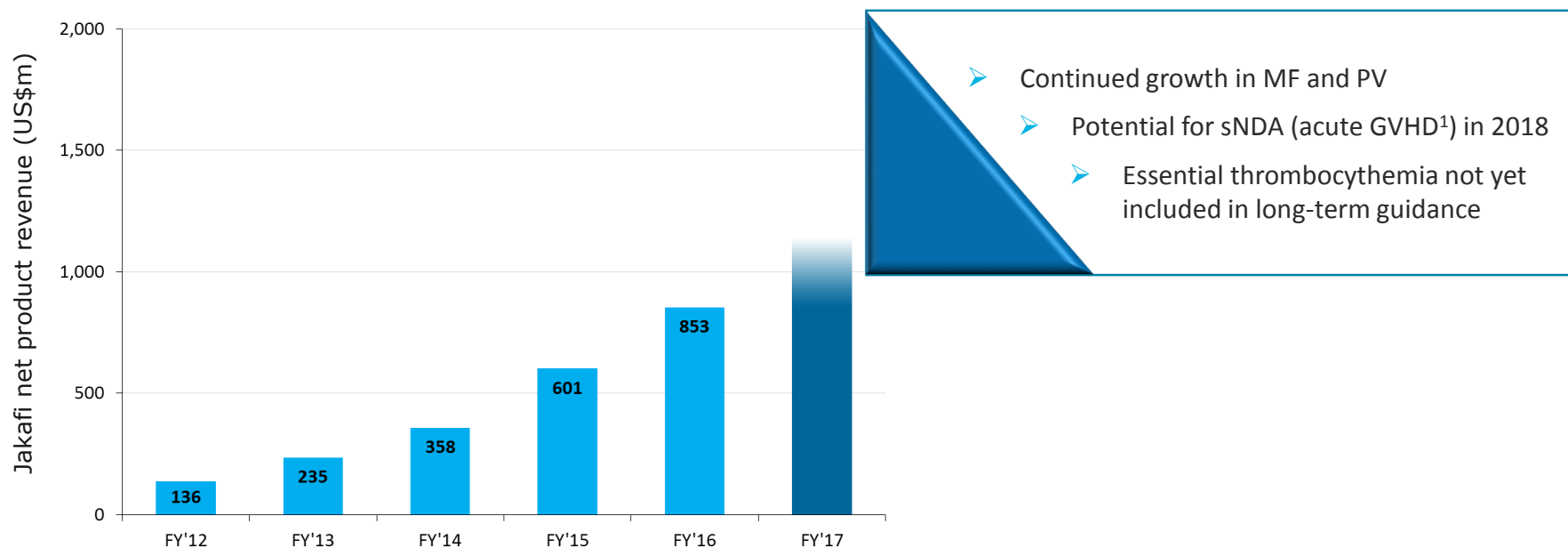
- Continued growth in both MF and PV
- Some inventory build in Q3

- **Increased FY 2017 guidance**

- Updated to range of \$1,125-1,135 million



# Substantial Long-term Potential of Jakafi®



1. sNDA would be filed seeking accelerated approval of Jakafi in patients with steroid-refractory acute GVHD

Jakafi (ruxolitinib) is marketed by Incyte in the US and is FDA approved for patients with intermediate or high-risk myelofibrosis (MF) and for patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea (PV)



# Clinical Development

**Steven Stein**

Chief Medical Officer



# Expanding Phase 3 Program for Epacadostat

Multiple indications to be evaluated with PD-1 and PD-L1 antagonists

## In combination with pembrolizumab

- Melanoma<sup>1</sup>
- Bladder, x2
- Kidney
- Head & neck
- Non-small cell lung cancer, x2

## In combination with nivolumab

- Head & neck
- Non-small cell lung cancer

## In combination with durvalumab

- Non-small cell lung cancer
  - Stage III disease, post CRT
  - 'PACIFIC' design
  - Initiation expected H1 2018

**Next wave of Phase 3 trials on track for initiation before the end of 2017**



1. ECHO-301 fully-recruited; data are expected in H1 2018

# Epacadostat: Pivotal Designs for RCC and NSCLC Now Available

All Phase 3 trials with pembrolizumab and nivolumab on track to begin in 2017

## Renal cell carcinoma

NCT03260894, ECHO-302

Approximately 600 patients

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**Pembrolizumab** 200 mg IV Q3W  
+ **Epacadostat** 100 mg BID PO

vs

**Sunitinib** 50 mg once daily PO  
-- or --  
**Pazopanib** 800 mg once daily PO

## Non-small cell lung cancer

PD-L1 +ve; NCT03322540, ECHO-305

Approximately 600 patients

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**Pembrolizumab** 200 mg IV Q3W  
+ **Epacadostat** 100 mg BID PO

vs

**Pembrolizumab** 200 mg IV Q3W  
+ **Placebo**

## Non-small cell lung cancer

PD-L1 all-comers; NCT03322566, ECHO-306

Approximately 1,000 patients

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**Pembrolizumab** 200 mg IV Q3W  
+ **Epacadostat** 100 mg BID PO  
+ **Platinum** doublet chemotherapy

vs

**Pembrolizumab** 200 mg IV Q3W  
+ **Placebo**  
+ **Platinum** doublet chemotherapy

vs

**Pembrolizumab** 200 mg IV Q3W  
+ **Epacadostat** 100 mg BID PO

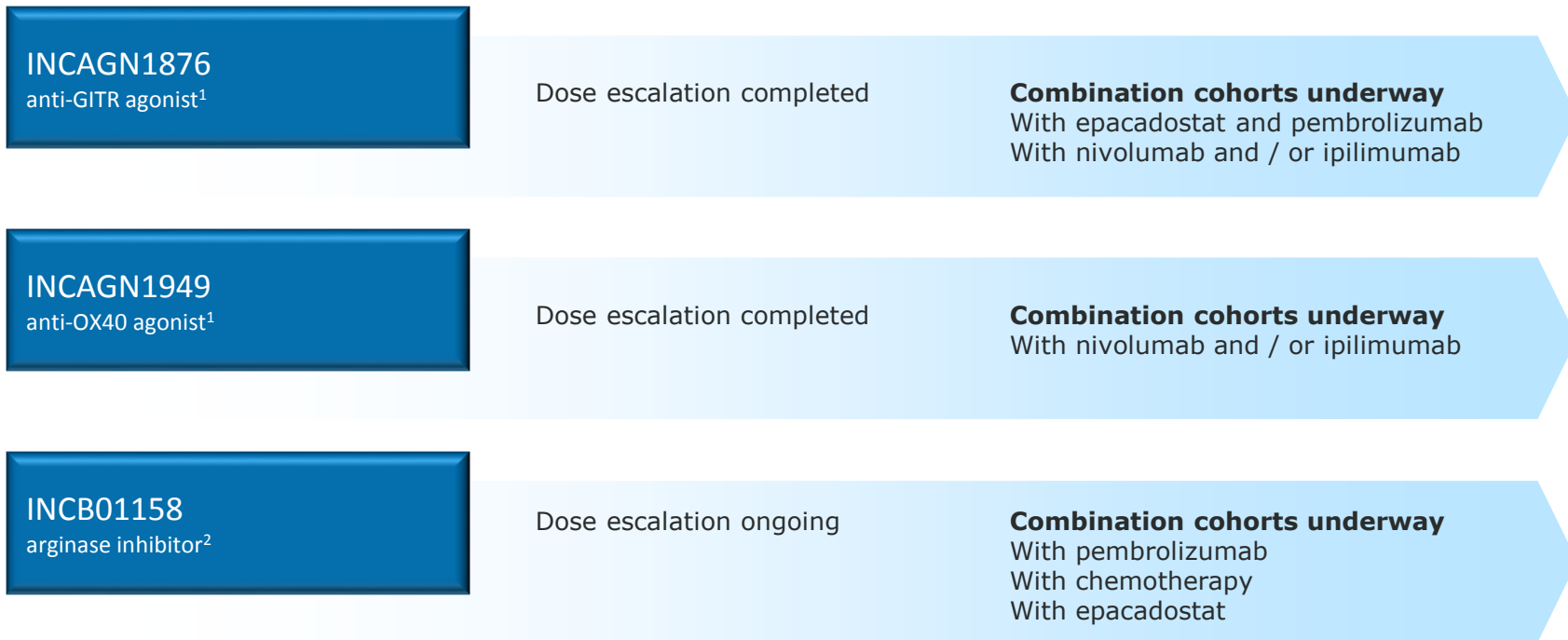


Co-primary endpoints for all three studies: Progression-free survival and overall survival



# Important Progress across Immuno-Oncology Development

## Three key targets being pursued with new combination studies



1. Discovery alliance with Agenus
2. Development in collaboration with Calithera; combination with pembrolizumab underway; combinations with chemotherapy and epacadostat planned

# Significant Potential within Targeted Therapies Portfolio

## JAK

ruxolitinib, itacitinib

### Broad Program in GVHD

Trials ongoing/planned for use in:

- Acute GVHD
- Chronic GVHD

In the following settings:

- Prophylaxis
- Treatment-naïve
- Steroid-refractory

### REACH1

Ruxolitinib in SR-aGVHD  
Pivotal data expected in H1 2018



SR-aGVHD = steroid-refractory acute graft versus host disease

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## FGFR1/2/3

INCB54828

### Two Key Development Programs

- Cholangiocarcinoma
- Bladder cancer

## PI3K Delta

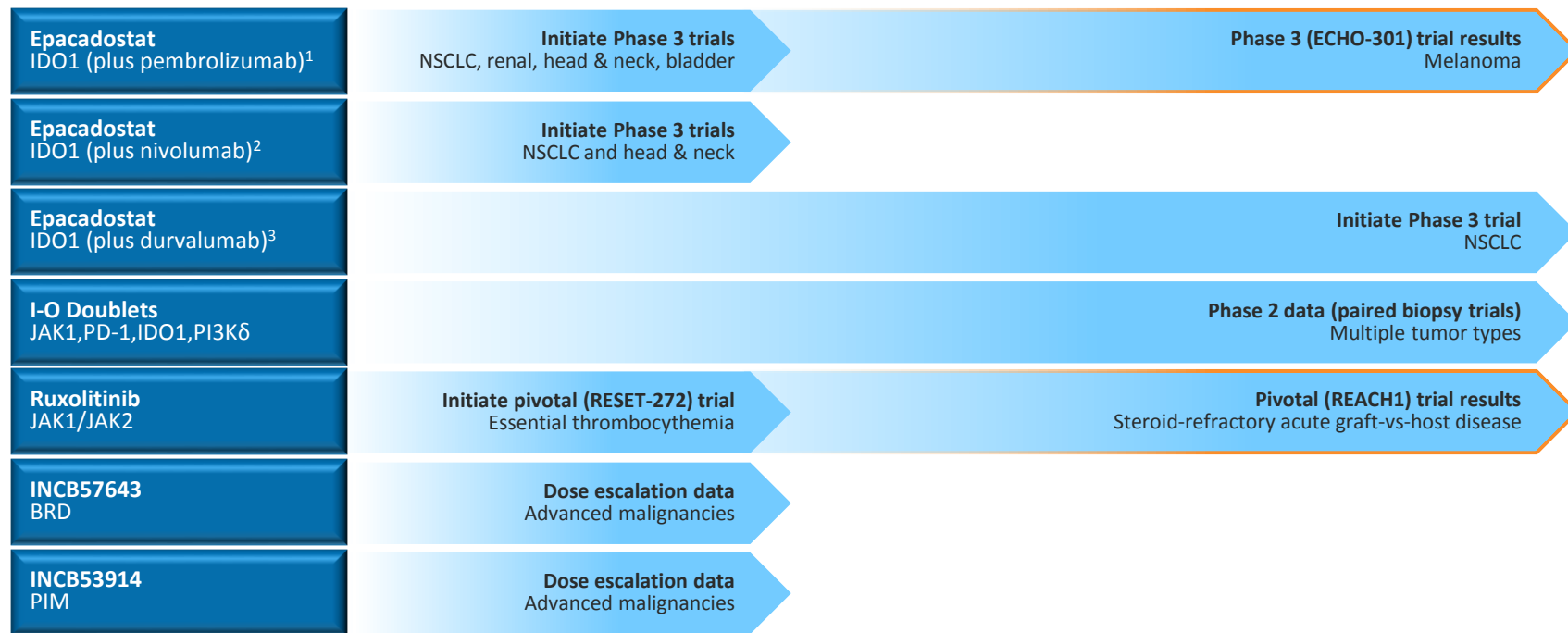
INCB50465

### Programs Across Four NHLs

- Diffuse large b-cell lymphoma
- Follicular lymphoma
- Marginal zone lymphoma
- Mantle cell lymphoma

# Upcoming Newsflow from Incyte

## Two Pivotal Trials Expected to Deliver Data in First-Half of 2018



1. In collaboration with Merck
2. In collaboration with BMS
3. In collaboration with AstraZeneca



# Financial Results

**David Gryska**

Chief Financial Officer



# Third-Quarter Financial Performance

Unaudited, in thousands	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
<b>Revenues:</b>				
Product revenues, net	\$ 322,029	\$ 236,623	\$ 878,503	\$ 632,006
Product royalty revenues	44,487	29,626	108,477	77,486
Contract revenues	15,000	3,214	105,000	69,643
Other revenues	18	6	80	86
<b>Total revenues</b>	<b>381,534</b>	<b>269,469</b>	<b>1,092,060</b>	<b>779,221</b>
<b>Costs and expenses:</b>				
Cost of product revenues (including definite-lived intangible amortization)	22,036	20,205	57,120	38,577
Research and development	269,612	143,184	879,423	420,276
Selling, general and administrative	91,271	75,776	268,577	207,166
Change in fair value of acquisition-related contingent consideration	(16,343)	8,012	(1,914)	10,283
<b>Total costs and expenses</b>	<b>366,576</b>	<b>247,177</b>	<b>1,203,206</b>	<b>676,302</b>
Income (loss) from operations	14,958	22,292	(111,146)	102,919
Interest and other income, net	5,555	1,188	10,884	3,818
Interest expense	(204)	(9,479)	(6,527)	(29,275)
Unrealized loss on long term investments	23,045	24,301	(2,343)	20,497
Expense related to senior note conversions	-	-	(54,881)	-
Income (loss) before provision (benefit) for income taxes	43,354	38,302	(164,013)	97,959
Provision (benefit) for income taxes	7,300	1,425	(500)	2,610
<b>Net income (loss)</b>	<b>\$ 36,054</b>	<b>\$ 36,877</b>	<b>\$ (163,513)</b>	<b>\$ 95,349</b>



# Updated FY 2017 Financial Guidance

	Current	Previous
Jakafi® net product revenue	\$1,125-1,135m	\$1,090-1,120m
Iclusig® net product revenue	\$60-65m	Unchanged
Royalties (Jakavi® & Olumiant®) <sup>1,2</sup>	No guidance given	Unchanged
Milestones	Up to \$145m	Unchanged
Cost of product revenue	\$75-80m	Unchanged
Research and development expenses	\$1,250-1,300m	\$1,050-1,150m
Selling, general and administrative expenses	\$340-360m	Unchanged
Change in fair value of acquisition-related contingent consideration	\$5-7m	\$30-35m
<b>Net income (loss)</b>	<b>\$(290-300)m</b>	<b>\$(180-200)m</b>

Guidance for research and development expenses includes \$359 million in upfront and milestone expenses related to the amended Agenus collaboration and the Merus and Calithera collaborations as announced in the first quarter of 2017, and the MacroGenics collaboration as announced in October 2017



1. Jakavi® (ruxolitinib) licensed to Novartis ex-US
2. Worldwide rights to Olumiant® (baricitinib) licensed to Lilly (approved in Europe and Japan, CRL from FDA in US, other global regulatory reviews ongoing)



# Science Drives Success

**Q&A**

