

# **Building Value through Innovative Medicines**

# Forward-looking Statements

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 ability to capitalize on potential opportunities for additional growth, to grow our top-line revenue quickly or at all and to develop any of compounds in our development portfolio successfully; the expectation that top-line growth could be accelerated by future launches and the anticipated and possible timing of future NDAs and sNDAs; our long-term Jakafi guidance; opportunities for the later-stage development portfolio to grow revenue and for us to achieve long-term success; the expected timing of the sNDA submission seeking approval of ruxolitinib in GVHD and whether or when approval will be obtained and whether we will launch ruxolitinib in this indication, if approved; the expected timing of data from the trial evaluating pemigatinib in patients with cholangiocarcinoma, and whether and when we will submit an NDA with respect thereto, and the expected timing of data from the trials of ruxolitinib cream in atopic dermatitis, pemigatinib in bladder cancer and ruxolitinib with INCB50465 in refractory myelofibrosis; our plans and expectations for development of and clinical trials our other product candidates, including the potential timing for regulatory submissions; our expected year-end level of cash and marketable securities; and our updated guidance for 2018.

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: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA; Incyte's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of Incyte's collaboration partners; the acceptance of Incyte's products and the products of Incyte's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended March 31, 2018. Incyte disclaims any intent or obligation to update these forward-looking statements.





# **Corporate Review**

**Hervé Hoppenot** 

Chief Executive Officer

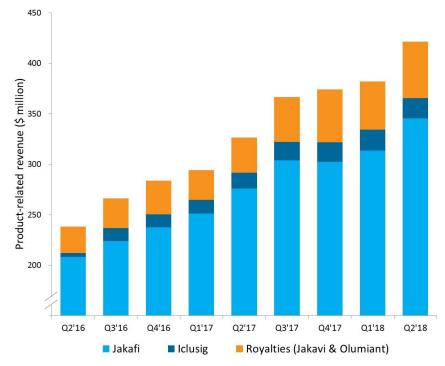
# Financially Positioned for Success Significant revenue momentum and a strong balance sheet

#### Four sources of revenue driving top-line growth

- Jakafi® +25% YoY
- Iclusig® +27% YoY
- Royalties (Jakavi® & Olumiant®) +61% YoY

#### Strong balance sheet<sup>1</sup>

- \$1.2 billion cash and equivalents
- \$100 million milestone from Lilly<sup>2</sup>
- Less than \$25 million debt





## Expanding and Consolidating Incyte's Leadership in MPNs

#### **Near-term upside opportunities**

- Improved duration of therapy in MPNs
- Greater penetration, especially in PV
- Potential launch in steroid-refractory GVHD

#### **Extending our leadership in MPNs**

- Novel formulations
- Ruxolitinib-based combinations
- Novel targets beyond JAK inhibition











**Long-term Jakafi® guidance** \$2.5 – 3 billion









## Revenue Acceleration Expected to be Driven by Multiple Products

- Global development and commercialization rights for new candidates
- Near-term potential to drive significant revenue growth
- Early-stage portfolio adds additional optionality

Optionality from early-stage research

#### Accelerate revenue growth

- Five new product candidates in addition to oral ruxolitinib
- Pursuing 15 new indications

#### **Extend leadership in MPNs**

- Novel targets beyond JAK inhibition
- Ruxolitinib-based combinations
- Novel formulations





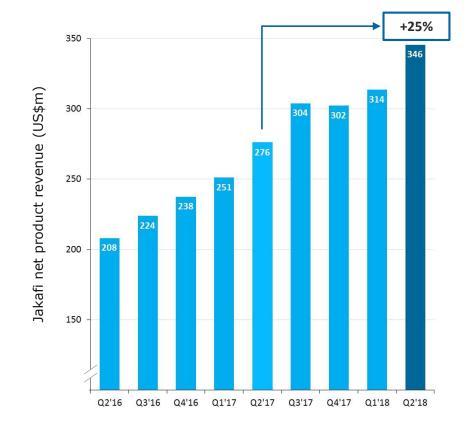
# **U.S. Commercial Update**

**Barry Flannelly** 

General Manager, U.S.

# Jakafi® Revenue Increased 25% over Q2 2017

- Significant revenue growth
  - 25% year-on-year increase
- Robust prescription demand
  - 16% YoY growth in total patients
- Reiterate FY 2018 guidance
  - Range of \$1.35-1.40 billion





### Launch Preparations Underway Following Successful REACH1 Results

- Primary endpoint met: sNDA submission for Jakafi® planned for Q3 2018
- Breakthrough Designation may provide for rapid regulatory review



#### Preparations for potential U.S. launch

- Incyte will launch Jakafi immediately upon approval
- The top 50 transplant centers by volume conduct over 70% of allogeneic stem cell transplants
- The US field force has been optimally sized and structured to support GVHD opportunity
- Pre-launch meetings with payers are being executed to obtain coverage



# **Clinical Development**

Reid Huber

Chief Scientific Officer

## Multiple Initiatives Ongoing to Enhance Benefits for MPN Patients

#### **Discovery initiatives**

#### **Novel target discovery**









#### **Development initiatives**

**Ruxolitinib-based combinations** 









#### Goals for next-generation MPN therapies:

- Improved patient outcomes: Greater spleen volume reduction and/or TSS scores
- Reduced disease burden: Molecular response, improved fibrosis and/or hematologic benefits
- Improved safety: Improved hematologic safety



11 TSS = Total Symptom Score

# Two Later-Stage Programs Evaluating INCB50465 (PI3Kδ) in Oncology

# Combination with Jakafi®

#### Refractory myelofibrosis

At study entry, patients needed to be treated with ruxolitinib for  $\geq$  6 months, and on a stable dose for  $\geq$  8 weeks

n = 78

- Primary endpoint: Change in spleen volume at week 12
- Secondary endpoints include:
   Total symptom score, change in spleen volume at week
   24, safety



Additional data anticipated in H2 2018

#### Relapsed / refractory FL

n = 100

- **Primary endpoint**: Objective response rate
- Secondary endpoints include: CR rate, duration of response, PFS, OS, safety

All three monotherapy trials are designed to enable registration in the US, if successful

#### Monotherapy

#### Relapsed / refractory MZL

previously treated with or without a BTK inhibitor

n = 120

#### • Primary endpoint: Objective response rate

Secondary endpoints include:
 CR rate, duration of response, PFS, OS, safety



Data anticipated in 2019

#### Relapsed / refractory MCL

previously treated with or without a BTK inhibitor

n = 120

- Primary endpoint: Objective response rate
- Secondary endpoints include:
   CR rate, duration of response, PFS, OS, safety



# Incyte is Conducting a Comprehensive Development Program Addressing Graft-Versus-Host Disease

**Prophylaxis** 

# **GRAYITAS**

Itacitinib (JAK1)
Phase I GRAVITAS-119 (n=60)

- Primary endpoint: Hematologic recovery at Day 28
- Secondary endpoints: GVHD incidence, Relapse, Survival, Time to engraftment, Safety
- Exploratory endpoints:
   Biomarkers

Acute GVHD

**Chronic GVHD** 

# **GRAVITAS**

#### Itacitinib

Phase 3 GRAVITAS-301 (n=436)

Primary endpoint: ORR Day 28 Key secondary: NRM Month 6 Itacitinib

Phase 3 GRAVITAS-309 (n=266)

Primary endpoint: ORR Month 6

Steroid Refractory: 2<sup>ND</sup> + line

Steroid Naïve:

Newly diagnosed

# **REACH**

#### Ruxolitinib

Phase 2 REACH1 (n=71)

Primary endpoint: ORR Day 28 Key secondary: DOR Month 6

Phase 3 REACH2 (n=308)

Primary endpoint: ORR Day 28 Key secondary: DOR Day 56 Ruxolitinib

Phase 3 REACH3 (n=324)

Primary endpoint: ORR Month 6



# Two Programs Assessing Tumor-Directed FGFR Inhibitor Therapy

#### Cholangiocarcinoma

Advanced/metastatic or unresectable cholangiocarcinoma (target n = 140) A: FGFR2 translocations (n=100)

B: other FGF/FGFR alterations (n=20)

C: without FGF/FGFR alterations (n=20)

pemigatinib QD (2 weeks on, 1 week off)

- Primary endpoint:
  - ORR in patients with FGFR2 translocations
- Secondary endpoints:

ORR in patients with other FGF/FGFR alterations Progression-free survival Safety and tolerability

Fibroliast Growth Factor
Receptor Inhibitor in Oncology
and Hemotology Triols

NDA anticipated in 2019

#### **Bladder cancer**

Metastatic or surgically unresectable urothelial carcinoma (target n = 240) A: FGFR3 mutations or fusions (n=100)

B: other FGF/FGFR alterations (n=40)

C: FGFR3 mutations or fusions (n=100)

pemigatinib QD (2 weeks on, 1 week off)

> pemigatinib 13.5 mg QD (continuous)

- Primary endpoint:
  - ORR in patients with FGFR3 mutations
- Secondary endpoints:

ORR in patients with FGF/FGFR alterations Progression-free survival and duration of response Safety and tolerability



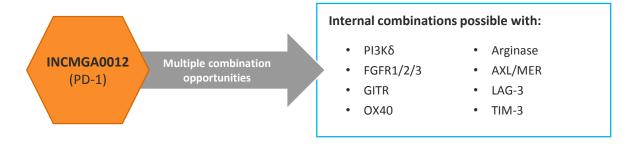
# INCMGA0012 has Potential in both Monotherapy and Combination Therapy Settings

#### Monotherapy development in three indications

MSI-high endometrial cancer	Merkel cell carcinoma	Anal cancer
MSI-related disease is well-recognized; CDx may not be required	Aggressive cancer with viral etiology; poor prognosis with current SoC	Virus-associated cancer (HPV or HIV) implies high mutational burden
Data expected 2020	Data expected 2020	Data expected 2021



#### Multiple opportunities for combination development





# Establishing a Specialty-focused Business Beyond Oncology (IAI)

To capitalize on our discovery and immunology expertise

#### Ruxolitinib cream

First-in-class, topical JAK/JAK2 inhibitor in dermatology

#### **INCB54707**

Oral JAK1 inhibitor; intent to explore indications of high unmet need that other JAK inhibitors have not yet entered

#### INCB50465

Oral PI3Kδ inhibitor; B-cell mediated and pathogenic antibodydriven diseases Atopic dermatitis Pivotal trial being planned

Vitiligo Phase 2 underway

Hidradenitis suppurativa

Phase 2 expected to begin in H2 2018

Pemphigus vulgaris

Autoimmune hemolytic anemia

Programs expected to begin in 2018

Sjögren's syndrome



IAI = Inflammation and Autoimmunity 16

#### **Discovery Development** Revenue Oncology Jakafi® ruxolitinib (tablets) INCB50465 IDO1 (ΡΙ3Κδ) Small molecules AXL/MER FGFR4 pemigatinib (FGFR1/2/3) Proof-of-concept PIM ICLUSIG\* (ponatinib) tablets itacitinib (JAK1) TIM-3 ARG Revenue Monoclonal ruxolitinib antibodies LAG-3 (JAK1/JAK2) **Royalties** OX40 INCMGA0012 S JAKAVI\* ruxolitinib (PD-1) GITR capmatinib **Bispecifics** (MET) Inflammation/autoimmunity olumiant. (Baricitinibi Tabletten ΡΙ3Κδ ruxolitinib

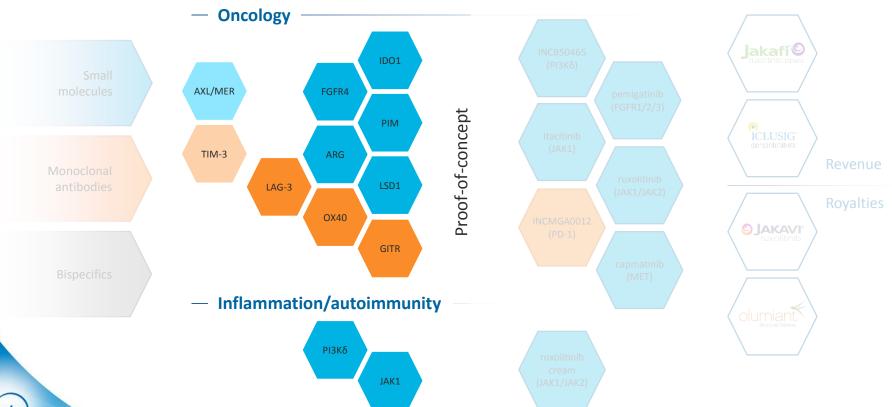
JAK1



cream

(JAK1/JAK2)

# Significant Optionality within the Earlier-Stage Portfolio As planned, anti-LAG-3 antibody entered clinical trials in the second quarter







# **Financial Results**

David Gryska

Chief Financial Officer

### Non-GAAP Adjustments

- The financial measures other than Non-GAAP net income presented in this presentation for the three and six months ended June 30, 2018 and 2017 have been prepared by the Company in accordance with U.S. Generally Accepted Accounting Principles ("GAAP").
- Management has chosen to present Non-GAAP net income for the three and six months ended June 30, 2018 and 2017 and to release both GAAP and Non-GAAP financial guidance for the year ending December 31, 2018 in belief that this Non-GAAP information is useful for investors, when considered in conjunction with Incyte's GAAP financial guidance.
- Management uses such information internally and externally for establishing budgets, operating goals and financial planning purposes. These metrics are also used to manage the Company's business and monitor performance. The Company adjusts, where appropriate, for both revenues and expenses in order to reflect the Company's core operations.
- The Company believes these adjustments are useful to investors by providing an enhanced understanding of the financial performance of the Company's core operations. The metrics have been adopted to align the Company with disclosures provided by industry peers.



2010 9 2017 Financial Parformance	Three Mont	hs Ended	Three Months Ended	
2018 & 2017 Financial Performance	June 30, 2018		June 30, 2017	
(unaudited, in thousands, except per share amounts)	GAAP	Non-GAAP	GAAP	Non-GAAP
Revenues:				
Product revenues, net	\$365,524	\$365,524	\$291,667	\$291,667
Product royalty revenues <sup>1</sup>	55,953	55,953	34,769	34,769
Milestone revenues	100,000	-	-	-
Other revenues	39	39	8	8
Total revenues	521,516	421,516	326,444	326,444
Costs and expenses:				
Cost of product revenues <sup>2</sup>	24,856	19,472	20,260	14,876
Research and development – ongoing <sup>3</sup>	278,089	253,294	201,786	178,908
Research and development – upfront consideration and milestone expenses	20,000	-	-	-
Selling, general and administrative <sup>3</sup>	108,029	96,218	90,066	79,200
Change in fair value of acquisition-related contingent consideration	7,303	-	7,073	-
Total costs and expenses	438,277	368,984	319,185	272,984
Income from operations	83,239	52,532	7,259	53,460
Other income (expense), net	5,808	5,808	4,066	4,066
Interest expense <sup>4</sup>	(398)	(98)	(384)	25
Unrealized loss on long term investments	(34,641)	-	(19,574)	-
Expense related to senior note conversions	-	-	(751)	-
Income (loss) before provision (benefit) for income taxes	54,008	58,242	(9,384)	57,551
Provision (benefit) for income taxes	1,614	1,390	3,100	551
Net income (loss)	\$52,394	\$56,852	\$(12,484)	\$57,000
Net income (loss) per share:				
Basic	\$0.25	\$0.27	\$(0.06)	\$0.28
Diluted	\$0.24	\$0.26	\$(0.06)	\$0.27

Product royalty revenues for the three months ended June 30, 2018 included \$47,101 from sales of Jakavi® by Novartis and \$8,852 from sales of Olumiant® by Lilly. Product royalty revenues for the three months ended June 30, 2017 included \$33,824 from sales of Jakavi® by Novartis and \$945 from sales of Olumiant® by Lilly.
 Non-GAAP excludes amortization of acquired product rights
 Non-GAAP excludes non-cash stock compensation from equity awards
 Non-GAAP excludes non-cash interest expenses related to convertible notes



2019 9 2017 Financial Parformance	Six Month	s Ended	Six Months Ended	
2018 & 2017 Financial Performance	June 30, 2018		June 30, 2017	
(unaudited, in thousands, except per share amounts)	GAAP	Non-GAAP	GAAP	Non-GAAP
Revenues:				
Product revenues, net	\$700,029	\$700,029	\$556,474	\$556,474
Product royalty revenues <sup>1</sup>	103,669	103,669	63,990	63,990
Milestone revenues	100,000	-	90,000	-
Other revenues	100	100	62	62
Total revenues	903,798	803,798	710,526	620,526
Costs and expenses:				
Cost of product revenues <sup>2</sup>	42,962	32,194	35,084	24,316
Research and development – ongoing <sup>3</sup>	568,748	519,731	400,597	356,250
Research and development – upfront consideration and milestone expenses	32,444	-	209,109	-
Selling, general and administrative <sup>3</sup>	229,527	205,714	177,295	157,285
Change in fair value of acquisition-related contingent consideration	13,988	-	14,429	-
Total costs and expenses	887,669	757,639	836,514	537,851
Income (loss) from operations	16,129	46,159	(125,988)	82,675
Other income (expense), net	10,270	10,270	5,213	5,213
Interest expense <sup>4</sup>	(783)	(186)	(6,323)	(845)
Unrealized loss on long term investments	(11,962)	-	(25,388)	-
Expense related to senior note conversions	-	-	(54,881)	-
Income (loss) before provision (benefit) for income taxes	13,654	56,243	(207,367)	87,043
Provision (benefit) for income taxes	2,400	2,000	(7,800)	919
Net income (loss)	\$11,254	\$54,243	\$(199,567)	\$86,124
Net income (loss) per share:				
Basic	\$0.05	\$0.26	\$(1.00)	\$0.43
Diluted	\$0.05	\$0.25	\$(1.00)	\$0.42

<sup>1.</sup> Product royalty revenues for the six months ended June 30, 2018 included \$88,438 from sales of Jakavi® by Novartis and \$15,231 from sales of Olumiant® by Lilly. Product royalty revenues for the six months ended June 30, 2017 included \$62,665 from sales of Jakavi® by Novartis and \$1,325 from sales of Olumiant® by Lilly.



Non-GAAP excludes amortization of acquired product rights
Non-GAAP excludes non-cash stock compensation from equity awards
Non-GAAP excludes non-cash interest expenses related to convertible notes

# 2018 and 2017 Non-GAAP Reconciliation (\$ thousands)

	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
GAAP Net Income (Loss)	\$52,394	\$(12,484)	\$11,254	\$(199,567)
Adjustments:				
Milestone revenues from new or existing partners	(100,000)	-	(100,000)	(90,000)
Upfront consideration and milestone expenses related to new or existing partners	20,000	-	32,444	209,109
Non-cash stock compensation from equity awards	36,606	33,744	72,830	64,357
Change in fair value of contingent consideration	7,303	7,073	13,988	14,429
Amortization of acquired product rights	5,384	5,384	10,768	10,768
Changes in fair value of equity investments	34,641	19,574	11,962	25,388
Non-cash interest expenses related to convertible notes	300	409	597	5,478
Expense related to senior note conversions	-	751	-	54,881
Tax effect of Non-GAAP adjustments	224	2,549	400	(8,719)
Non-GAAP Net Income	\$56,852	\$57,000	\$54,243	\$86,124



2018 Financia	l Guidance Updates	Current guidance	Previous guidance
	GAAP and Non-GAAP Jakafi® net product revenues	\$1,350 - \$1,400 million	No change
Revenue	GAAP and Non-GAAP Iclusig® net product revenues	\$80 - \$85 million	No change
	GAAP Cost of product revenues	\$85 - \$95 million	No change
Cost of Product Revenues	Non-GAAP Adjustment: Amortization of acquired product rights for Iclusig	\$21 million	No change
	Non-GAAP Cost of product revenues	\$64 - \$74 million	No change
Research & Development Expenses	GAAP Research and development expenses	\$1,150 - \$1,250 million	No change
	Non-GAAP Adjustment: Stock-based compensation	\$110 - \$115 million	No change
	Non-GAAP Adjustment: Upfront consideration and milestones related to collaborations	\$32 million	\$27 million
	Non-GAAP Research and development expenses	\$1,008 - \$1,103 million	\$1,013 - \$1,108 million
Selling, General &	GAAP Selling, general and administrative expenses	\$390 - \$410 million	No change
Administrative Expenses	Non-GAAP Adjustment: Stock-based compensation	\$50 - \$55 million	No change
	Non-GAAP Selling, general and administrative expenses	\$340 - \$355 million	No change
	GAAP Change in fair value of acquisition-related contingent consideration	\$30 million	No change
Contingent	Non-GAAP Adjustment: Change in fair value of estimated future royalties relating to sales of Iclusig® in licensed territory	\$30 million	No change
Consideration	Non-GAAP Change in fair value of acquisition-related contingent consideration	\$0 million	No change



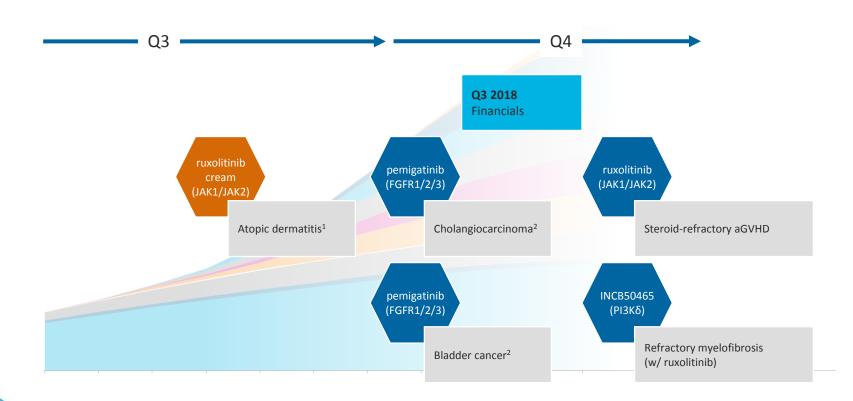


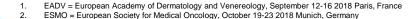
# **Expected Newsflow**

**Hervé Hoppenot** 

Chief Executive Officer

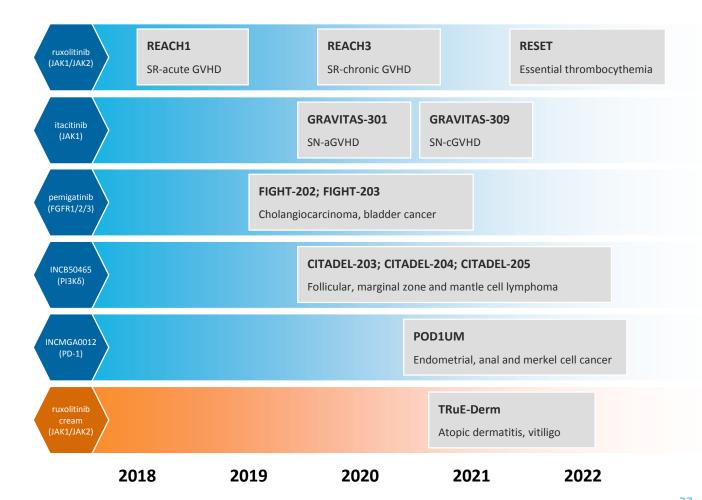
# Five Important Data Sets Expected Before the End of 2018





# Potential for multiple launches in the near-term









Q&A