



(Nasdaq: INSY)

A photograph of a laboratory setting. In the foreground, a row of clear microcentrifuge tubes sits on a surface. A pipette is shown in the process of dispensing a small amount of clear liquid into the tube on the far right. The background is a soft-focus blue, suggesting a laboratory environment. The image is partially obscured by a dark blue diagonal overlay on the left side.

# Q3'18 Earnings Supplemental Slides

November 5, 2018

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# Recent Progress on Strategic Priorities

Continued execution of strategy to transform the company into a leader in pharmaceutical cannabinoids and spray technology

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## Resolve Government Investigations and Rebuild Reputation

- Announced **DOJ** settlement agreement in principle, consistent with previous public statements/disclosures
- Continued working with state **attorneys general** to resolve outstanding claims
- Confirmed **SEC** has concluded investigation and does not intend enforcement action

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## Strengthen the Foundation and Enhance Execution

- Appointed Elizabeth Bohlen to **Board** of Directors
- Added Mark Nance to **management** team as Chief Legal Officer and General Counsel
- Optimized Commercial organization to control **op-ex** in line with lower revenue

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## Advance and Develop Diverse Pipeline to Drive Future Growth

- Received 'Fast Track' designation from FDA for **epinephrine** nasal spray
- Continued enrolling company-sponsored **CBD** studies:
  - childhood *absence* epilepsy
  - Prader-Willi syndrome
  - infantile spasms
- Expanded **CMCR** collaboration with two additional studies:
  - early psychosis
  - anxiety in anorexia nervosa
- Completed PK study of **dronabinol** inhalation

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## Stabilize and Grow Marketed Portfolio

- Commenced review of **strategic alternatives** for opioid-related assets
- Signed **licensing agreement** with Lunatus to commercialize SUBSYS® in the Middle East
- Received **FDA approval** of sNDA for SYNDROS® to expand label, enabling delivery of drug through feeding tube

Supported by strong culture of compliance

- **TIRF market continues to be under pressure**
  - Efforts by various constituents to reduce opioid use
  - Concern among cancer patients regarding fentanyl
- **SUBSYS<sup>®</sup> remains branded TIRF leader**
  - 27.2% TRx share
  - 31.6% unit share
- **Over 50% of new patients prescribed TIRF product receive Rx for SUBSYS<sup>®</sup>**

# Q3'18 Financial Highlights

	Q3'18	Q2'18	Q3'17 As Revised
<b>Net Revenue</b>	\$18.3M	\$23.5M	\$30.7M
<b>Gross Margin</b>	87.0%	84.7%	75.6%
<b>Sales &amp; Marketing</b>	\$7.4M	\$9.1M	\$12.8M
<b>Research &amp; Development</b>	\$14.5M	\$16.5M	\$19.6M
<b>General &amp; Administrative</b>	\$8.9M	\$10.9M	\$11.3M
<b>Legal</b>	\$16.0M	\$11.1M	\$4.4M
<b>Income Tax Expense (Benefit)</b>	\$0.2M	\$0.1M	(\$9.0M)
<b>Adjusted EBITDA</b>	(\$26.0M)	(\$22.5M)	(\$18.4M)
<b>Liquidity (Cash &amp; Investments)</b>	\$113.0M	\$123.5M	\$177.2M

\* Please see a reconciliation of our GAAP to Non-GAAP financials in our quarterly press release

# Q3'18 Financial Highlights

	Q3'18	Q3'17 As Revised	Increase / (Decrease)
Sales & Mktg	\$7.4M	\$12.8M	-42.2%
R&D	\$14.5M	\$19.6M	-26.0%
G&A	\$8.9M	\$11.3M	-21.2%
<b>Sub-Total Before Legal</b>	<b>\$30.8M</b>	<b>\$43.7M</b>	<b>-29.5%</b>
Legal Costs	\$16.0M	\$4.4M	263.6%
Settlements	\$0.0M	\$150.9M	-100.0%
<b>Total Operating Expense</b>	<b>\$46.8M</b>	<b>\$199.0M</b>	<b>-76.5%</b>

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# Deep Pipeline to Drive Long-Term Growth

	Drug Candidate	Disease State	Non-Clinical	Phase 1	Phase 2	Phase 3	Submit	Approval
<b>CANNABINOIDS</b>	<b>Cannabidiol (CBD)</b> Oral Solution	(i) Childhood <i>Absence</i> Epilepsy	Ph 2 Enrolling (n=30)					
		(ii) Infantile Spasms	Ph 3 Initiated (n=190)  Orphan Drug Designation Granted Aug 2015					
		(iii) Prader-Willi Syndrome	Ph 2 Enrolling (n=66)  Fast Track Designation Granted Dec 2017					
	<b>Dronabinol</b> Inhalation	Anorexia in Cancer	In Dev  PK Study Completed Sept 2018					
<b>SPRAYS</b>	<b>Naloxone*</b> Nasal Spray	Opioid Overdose	PK Completed  NDA Filing 1Q 2019**					
	<b>Epinephrine*</b> Nasal Spray	Anaphylaxis	PK Completed  Fast Track Designation Granted Aug 2018					
	<b>Buprenorphine/Naloxone</b> Sublingual Spray	Opioid Dependence	In Dev 					
	<b>Buprenorphine</b> Sublingual Spray	Moderate-to-Severe Acute Pain	NDA Filed  CRL Rec'd July 2018					

\* Pursuing 505(b)2 bioequivalence approach for potential approval

\*\* FDA requires additional juvenile nonclinical toxicity studies as part of the pediatric plan

# Collaborative CBD Trials Under Consideration

- ✓ **Autism**
  - ✓ **Early Psychosis**
  - ✓ **Anxiety in Anorexia Nervosa**
- Collaborating with University of California (UC) San Diego School of Medicine's Center for Medicinal Cannabis Research (CMCR)



- **Childhood Schizophrenia/ Early Psychosis**
- Orphan Drug Designation  
Possible collaboration

- **Opioid Use Disorder**
- Possible collaboration

- ✓ **Cocaine Addiction**
- Ongoing Collaboration with University of Montreal and Canadian Institutes of Health Research



- **Post-Traumatic Stress Disorder**
- Possible collaboration

## Year-to-Date 2018

- ✓ Began enrolling three clinical studies of CBD:
  - 1) childhood *absence* epilepsy (Phase 2)
  - 2) Prader-Willi syndrome (Phase 2)
  - 3) infantile spasms (Phase 3)
- ✓ Conducted proof-of-concept study for dronabinol inhalation, targeting anorexia in cancer as potential indication, and reported results
- ✓ Advanced epinephrine program:
  - 1) Received Fast Track designation
  - 2) Completed End-of-Phase 2 meeting
  - 3) Reported results from proof-of-concept study
- ✓ For naloxone program, initiated FDA-required nonclinical juvenile toxicity studies
- ✓ Received FDA approval of supplemental NDA for SYNDROS® to expand label, enabling use of product with feeding tubes for patients with cancer and AIDS

## Upcoming

- Present results from long-term safety study of CBD in refractory pediatric epilepsy at AES meeting in early December
- Report results of Phase 2 clinical trial of CBD in childhood *absence* epilepsy
- File NDA for naloxone nasal spray as potential treatment for opioid overdose



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