

*Developing Disruptive Therapeutics  
for the Treatment of Pancreatic Diseases*

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*2017 Marcum Microcap Conference  
June 15/16, 2017  
OTCQB: SNBP*



# *Forward Looking Statements Disclaimer*

*Certain statements in this presentation are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are provided under the protection of the safe harbor for forward-looking statements provided by that Act. Forward-looking statements are based on current expectations of future events and often can be identified by words such as “anticipates,” “believes,” “estimates,” “expects,” “future,” “intends,” “plans,” “project,” “target,” or other words of similar meaning or the use of future dates. Examples of forward-looking statements in this presentation include statements regarding the safety, effectiveness and benefits of SBP-101; the timing of enrollments in and completion of our Phase 1 clinical trial for SBP-101; anticipated submission and acceptance of an IND for pancreatitis by the US FDA; potential business opportunities; future fundraising or capital requirements; and expected financial or operating results. Uncertainties and risks may cause our actual results to be materially different than those expressed in or implied by our forward-looking statements. Such uncertainties and risks include, among others, risks associated with our Phase 1 clinical trial for SBP-101, including administration, enrollment, completion and results; safety and efficacy of our drug candidates; regulatory requirements and changes; the availability of and requirements for financial and other resources necessary to execute our business plans; difficulties maintaining and obtaining key personnel, competitive conditions in our primary market; and our ability to establish and protect our intellectual property rights. More detailed information on these and other factors that could affect our actual results are described in our SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2016 and, most recently, in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017. We encourage you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this presentation. The forward-looking statements provided in this presentation speak only as of the date of this presentation and, except to the extent required by law, we undertake no obligation to update any forward-looking statement because of new information, future events or other factors.*



# Sun BioPharma, Inc. - Highlights

- Pancreatic ductal adenocarcinoma (PDA) and pancreatitis are large, urgent, unmet medical needs with very limited treatment options
- SBP-101, a polyamine analogue, exploits natural affinity of exocrine pancreas for polyamines to disrupt normal polyamine metabolic process
- Natural selectivity minimizes toxicity to islet cells and other non-target tissues
- Phase 1a safety/dose escalation study underway
- Early signals of efficacy (stable disease) observed in third, fourth and fifth cohorts

Program	Collaborators	Discovery	Pre-IND	Phase 1
<b>SBP-101</b> Advanced or Metastatic Pancreatic Cancer	The Mayo Clinic & Honor Health, Scottsdale, AZ; Adelaide Cancer Centre & Austin Health Cancer Trials Centre, Australia			
<b>SBP-101</b> Chronic or Recurrent Acute Pancreatitis	University of Minnesota			

**New Synthetic Polyamine Selectively Targets Exocrine Pancreas**



# *Executive Management Team*

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Michael T. Cullen, MD, MBA - Co-Founder and Executive Chairman

- ❑ MGI Pharma, GD Searle, SunPharm, Omnicare, 3M

David B. Kaysen - CEO & Director

- ❑ Uroplasty, Rehabicare, Diametrics Medical

Scott Kellen - VP of Finance & CFO

- ❑ Kips Bay Medical, Transoma Medical, ev3 Inc., Deloitte & Touche

Suzanne Gagnon, MD - Chief Medical Officer & Director

- ❑ ICON, Rhone Poulenc Rorer (Sanofi), Omnicare, Luitpold Pharmaceuticals

Thomas X. Neenan, PhD - Co-Founder & Chief Scientific Officer

- ❑ Sideris, Genzyme, GelTex Pharmaceuticals

- ✓ **10+ FDA drug approvals, hematology/ oncology success.**
- ✓ **10-20+ year relationships of CMC, pharmacology, toxicology, regulatory, clinical, operations, program mgmt, writing, mfg ops and business team leadership.**
- ✓ **20+ years of public markets and shareholder value creation experience.**

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## **Demonstrated Track Record of Value Creation**

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# Market Opportunity

## ▶ Pancreatic cancer – US 53,000 cases/year

- High unmet need due to high mortality and short life expectancy
- 95% pancreatic ductal adenocarcinoma (PDA)
- 7% 5-year survival rate
- Current Rx Median Survival Benefits  
6 weeks, 10 days, 7 weeks, 16 weeks

## ▶ Pancreatitis – no organ-specific Rx

- Acute – 300,000 US hospitalizations/year
- Recurrent Acute ~ 50% of acute hospitalizations
- Chronic – 30,000 US hospitalizations/year
- Direct annual cost of ~ \$3 billion
- 2-5% mortality rate

Type	Incidence*	Deaths*	5-year Survival#
Lung	224,390	158,080	17.7%
Colon	134,490	49,190	65.1%
Pancreas	53,070	41,780	7.7%
Breast	246,660	40,450	89.7%
Prostate	180,890	26,120	98.9%

- Estimates for 2016 based upon 2009-2013 data
- Source: <http://seer.cancer.gov/statfacts/>

Source: Afghani, Pandol, et al – *Pancreas*, November 2015

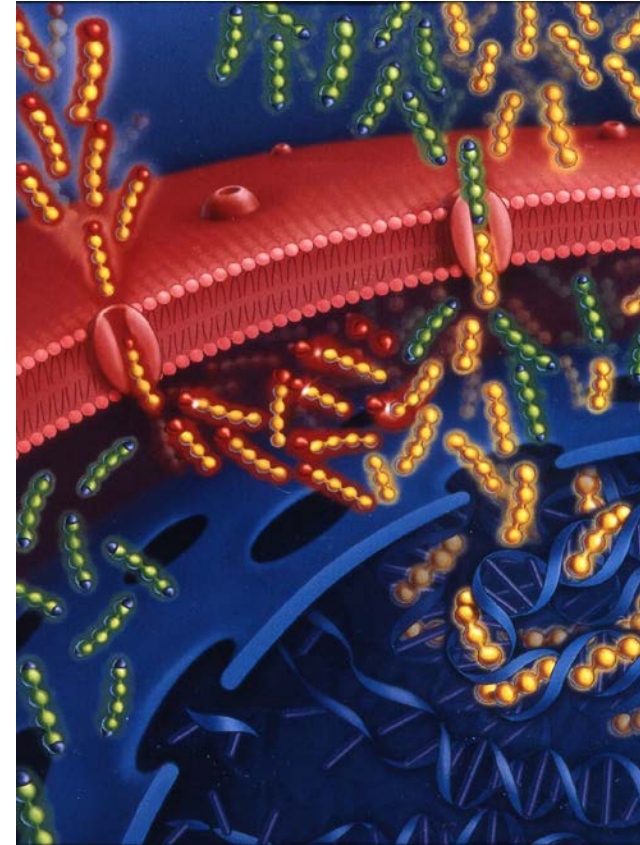
## Two Large Unmet Medical Needs in Pancreatic Disease



# *Mechanism of Action SBP-101: Polyamine Analog*

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- ▶ SBP-101 is an analogue of a naturally occurring polyamine (PA)
- ▶ Increased PA levels found in pancreatic ductal adenocarcinoma (PDA) cells (uptake of PAs accelerated)
- ▶ An excess of SBP-101 “pseudo-polyamine” disrupts normal metabolic process
- ▶ Disruption of the natural intra-cellular metabolic process by SBP-101 triggers programmed cell death (apoptosis)



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**Fundamentally Different Approach to Impact Pancreatic Cancer**

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# *Exocrine Pancreas Specific, Combo Potential*

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- ▶ Exocrine Pancreas specific effect
  - ❑ Injectable (sc) sustained dosing has cumulative effect which induces programmed cell death in exocrine pancreas (acinar/ductal cells)
  - ❑ No effect on islet cells or insulin/glucose levels, glucose tolerance tests
- ▶ Minimal potential for drug interactions
  - ❑ No protein binding
  - ❑ No hepatic (liver) enzyme induction or inhibition
- ▶ Anticipate good safety profile and no chemotherapy-type side effects
  - ❑ Avoids bone marrow suppression, nausea, vomiting, neuropathy, diarrhea
  - ❑ Transaminitis, GI motility impairment
  - ❑ Progressing through Phase 1a Clinical Trial:
    - ✓ Safety Study
    - ✓ Early Signals of efficacy
    - ✓ Goal is to Determine maximum tolerated dose (MTD)

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**Selective Uptake Enhances Safety Profile, Enables Rx Combinations**

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# *SBP-101 in Pancreatic Cancer*

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- ▶ Preclinical studies show both superior efficacy of SBP-101 by itself and additive efficacy in combination with standard Rx\*
- ▶ Compelling data in 6 human pancreatic cancer cell lines
- ▶ Early signals of efficacy in First-in-Human Phase 1a clinical trial
- ▶ 3 different *in vivo* human pancreatic cancer xenograft models
- ▶ Standard Rx\* *toxicity not observed* with SBP-101: avoids bone marrow suppression, nausea, vomiting, neuropathy, diarrhea
- ▶ *SBP-101 combination potential*
  - ✓ Additive efficacy
  - ✓ No overlapping toxicity
  - ✓ No drug interaction

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**Evidence Suggests Safety, Efficacy & Potential for Combination Rx**

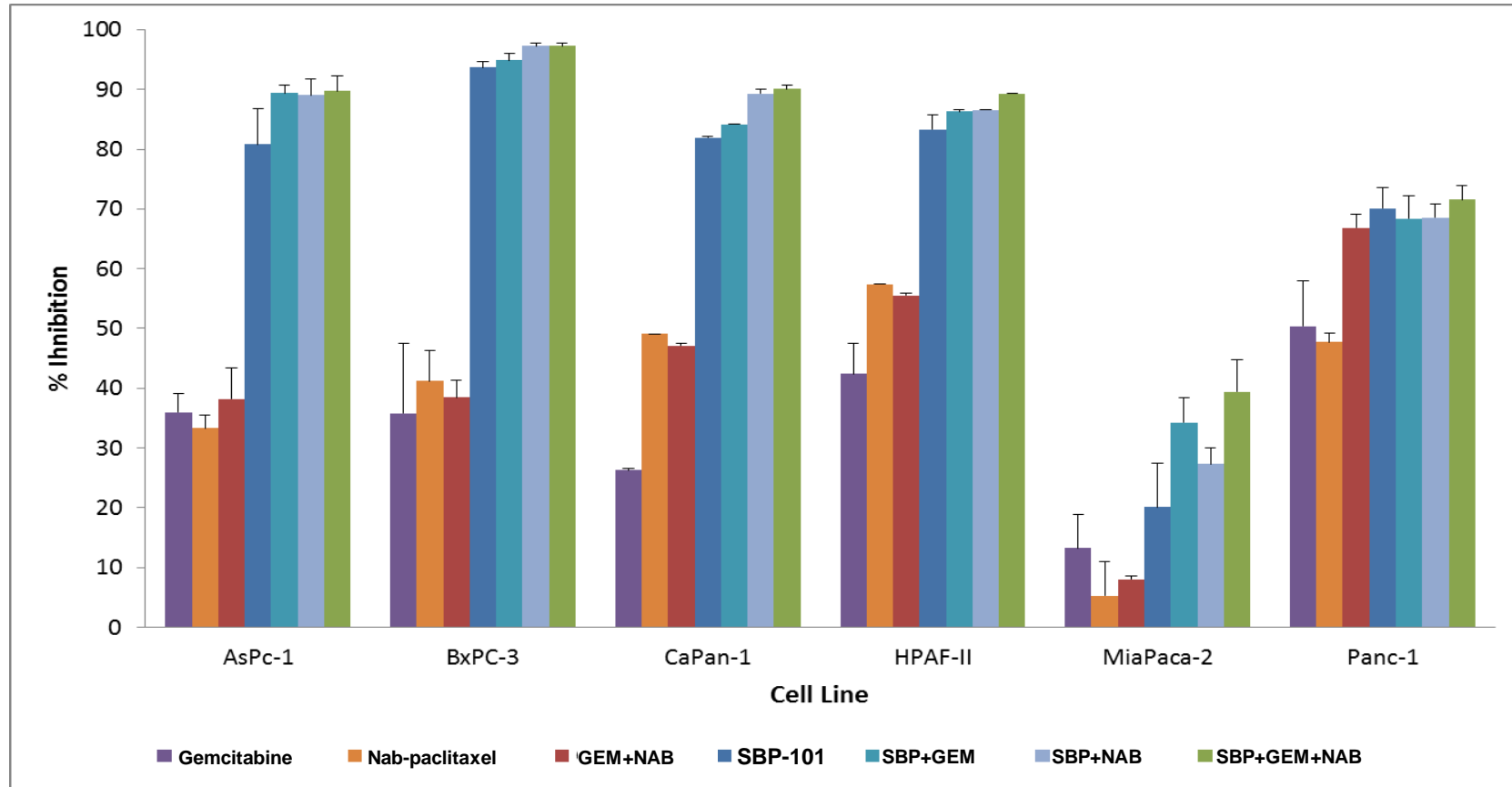
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\*gemcitabine and nab-paclitaxel





# *SBP-101 vs. gemcitabine, nab-paclitaxel, combos*



Maximum % growth inhibition (mean±SE) at 96 hours with 10 μM SBP-101 alone and in combination with gemcitabine and/or nab-paclitaxel in 6 human pancreatic cancer cell lines

Source: Baker CB et al Pancreas 2015;44(8) 1350



# *SBP-101 in Healthy Beagles*

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- ▶ Protocol: 4.3mg/kg/day x 14 days
- ▶ Outcomes:
  - ❑ Exocrine pancreatic atrophy
    - ✓ Cumulative dose
    - ✓ Latent (delayed) effect
    - ✓ Exocrine pancreatic insufficiency (“EPI”)
  - ❑ No inflammatory response
  - ❑ Preservation of islet cells with normal blood glucose & insulin levels

Cumulative exposure to SBP-101 produced a  
**“Pharmaceutical Total Pancreatectomy with Islet Auto  
Transplantation (TP-IAT)”**

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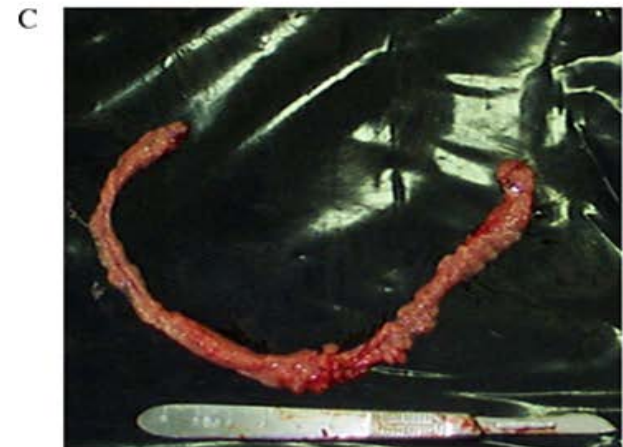
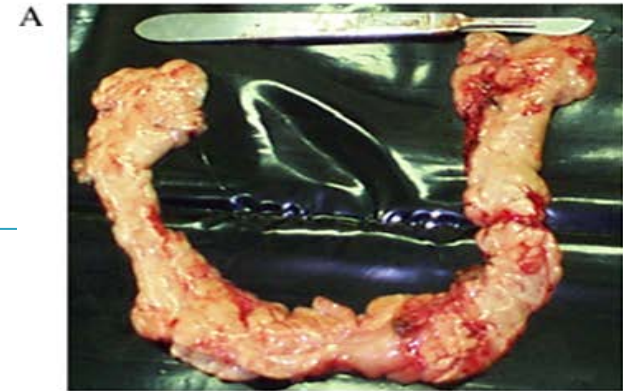
**SBP-101 Induced Acinar & Ductal Cell Apoptosis**

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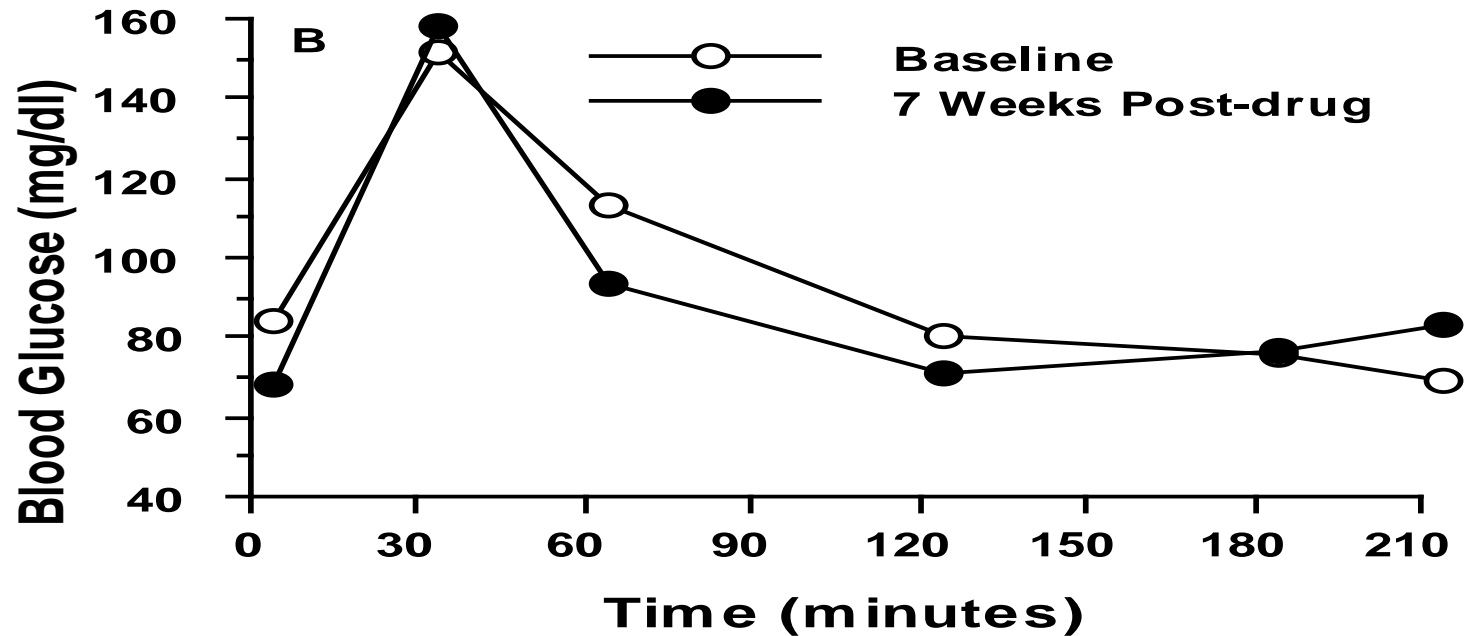


# Gross Morphology of Beagle Pancreata Excised at Necropsy

- ▶ Panel A: Untreated control dog.
- ▶ Panels B and C:
  - ❑ Dogs received 4.3 mg/kg/day SBP-101 x 14 days
  - ❑ Sacrificed on days 57 and 61, respectively.



# Glucose Tolerance Test in Dogs (4.3 mg/kg SC for 14 d)



**Glucose Tolerance Unchanged 7 Weeks After Dosing**



# *SBP-101 – PDA Clinical Progress*

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## **Pancreatic Cancer:**

- ▶ US Orphan Drug status granted Q3 2014
- ▶ FDA IND accepted for Phase 1 study - Q3 2015
- ▶ Australian HREC/TGA accepted CTN Q4 2015
- ▶ Completed first patient cohort Q2 2016
- ▶ Early signals of efficacy observed in third, fourth and fifth cohorts – stable disease in 6 out of 11 patients – Q2 2017
- ▶ Four centers recruiting patients
- ▶ Expect MTD finding late Q3 of 2017

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## **Orphan Drug Status for PDA & Approaching MTD**

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# *TOP LINE INTERIM RESULTS – PHASE 1A STUDY*

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- ▶ 5 Cohorts totaling 25 patients have been completed as of May 15, 2017
- ▶ Seeking to approach the Maximum Tolerated Dose (MTD) with next cohort of 3 patients
  - ❑ One patient completed first cycle dosing, and 1 in screening
  - ❑ This dose level will be at the same level as Cohort 4
  - ❑ Expected to complete this cohort by August
- ▶ Review of data for all 25 patients
  - ❑ 20 of 25 patients were evaluable for preliminary signals of efficacy at 8 weeks
    - ✓ 6 of 20 (30%) had Stable Disease (RECIST criteria)
  - ❑ 9 of 24 patients (38%) had reductions in CA 19-9

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## **Approaching Maximum Tolerated Dose**

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# *TOP LINE INTERIM RESULTS – PHASE 1A STUDY*

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- ▶ Best Response at 8 Weeks: (8 patients with total Cumulative Doses equivalent to Cohorts 3 & 4)
  - ❑ 7 of 8 were evaluable for tumor assessment
    - ✓ 3 of 7 (43%) had stable disease (RECIST criteria)
  - ❑ 4 of 8 (50%) had reductions in CA 19-9 tumor marker
  - ❑ Median survival in this group was 4.1 months
    - ❖ 6 patients (75%) have exceeded 3 months of overall survival (OS)
    - ❖ 4 have exceeded 4 months of OS
    - ❖ At least 2 have exceeded 6 months of OS
    - ❖ Certain patients continue to be followed for OS

Note: Study patients - advanced stage pancreatic cancer & heavily pre-treated

While Phase 1a is a safety study, this data is encouraging

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## **Early Signals of Efficacy**

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# Physician Collaborators

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- ▶ Dan Von Hoff, M.D. - TGen/Mayo Clinic, Scottsdale, AZ
- ▶ James Abbruzzese, M.D. – Duke Cancer Institute, Durham, NC
- ▶ David Goldstein, M.D. – Prince Henry & Prince of Wales Hospital, Sydney, Australia
- ▶ Ashok Saluja, Ph.D.\* - Laboratory U of Miami\*\*
  - ❑ Mechanism of action (MOA) pancreatic cancer
  - ❑ Pancreatitis Models
- ▶ Steve Pandol, M.D.\* – Laboratory Cedars-Sinai
  - ❑ Human acinar cells, Pancreatitis models

*“Our team at the University of Miami is excited about the opportunity to work with the compound SBP-101. The compound’s novel mechanism of action is showing promise as a candidate for the largely unmet medical needs pertaining to the treatment of pancreatic cancer and pancreatitis.”*

*-Dr. Ashok Saluja*

\* American Pancreatic Association Past President

\*\* formerly U of Minnesota Surgery Department lab

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## Enthusiastically Supported by Leading Pancreatic KOLs

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# *Institutional Collaborators*

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## Research Partners:



## Clinical Sites - US:



## Clinical Sites - Australia:



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**World Renowned Research and Clinical Institutions**

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# *Sun BioPharma Inc. Intellectual Property*

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## **Issued Patent:**

- ▶ **US Patent No 6,160,002** is a method of use patent that covers the use of SBP-101 for the chemical resection of the exocrine portion of the pancreas, issued on December 12, 2000, expiring on July 19, 2019 (licensed from the University of Florida)

## **Patents Pending:**

- ▶ **U.S Patent Application No. 62/238,916 and Int'l Application No. PCT/US2016/55888** - method applications covering the use of SBP-101 to treat pancreatitis

## **US Orphan Drug Status**

- ▶ Granted by US in 2014 for pancreatic cancer (7 years market exclusivity)
- ▶ Expected in EU & Japan (10 and 7 years, respectively)
- ▶ Exclusivity begins with marketing authorization/approval

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**Patents and Orphan Drug Designation Provide Substantial Protection**

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## *Upcoming Milestones – PDA & Pancreatitis*

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- ▶ Expect MTD finding – Q3 2017
- ▶ Phase 1a cancer safety data available – Q3 2017
- ▶ Initiation of second cancer trial – Q4 2017
- ▶ IND submission for pancreatitis – Q4 2017 to Q1 2018\*
- ▶ IND acceptance for pancreatitis – Q2 2018
- ▶ First patients enrolled pancreatitis phase 1 clinical – Q2 2018
- ▶ Early results from second cancer trial – Q2/3 2018
- ▶ Early data signal on pancreatitis – Q4 2018

\* Timing for pancreatitis development dependent upon financing

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**Multiple Clinical Data Events Expected to Support News Flow**

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# Capitalization: As of March 31, 2017

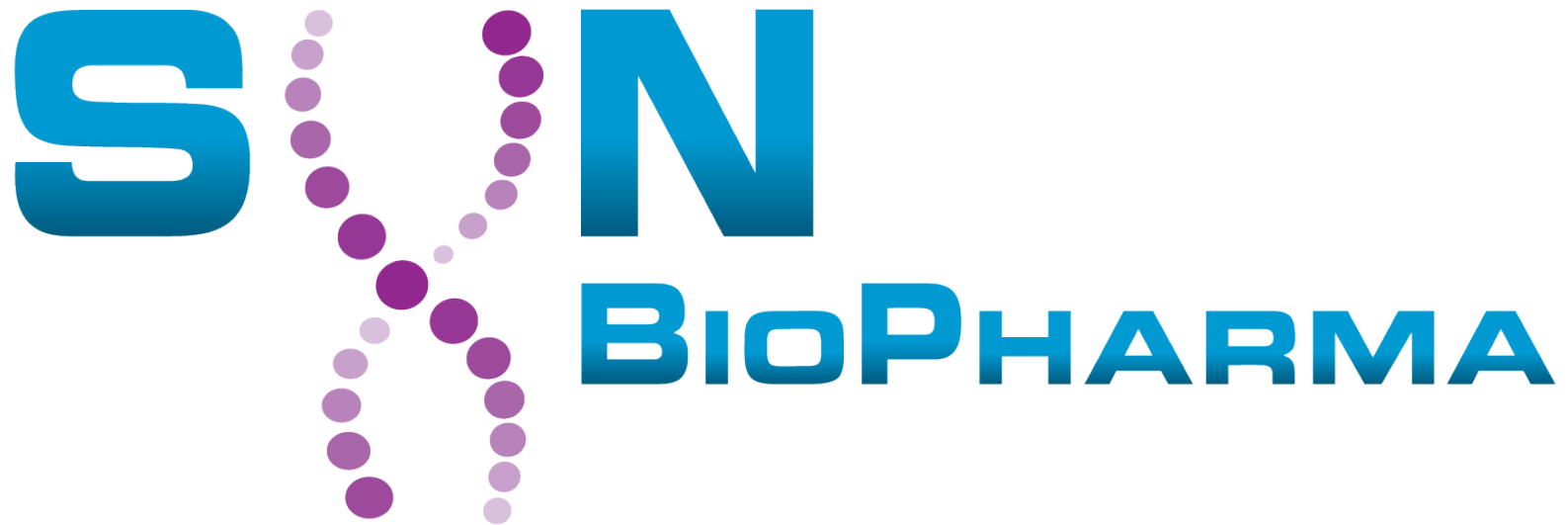
<b>Debt</b>	<b>Amount (\$)</b>
Floriday Start-Up Loan	\$ 300,000
Convertible notes (mandatory convert on next financing)	\$ 3,100,500
<b>Total debt</b>	<b>\$ 3,400,500</b>

<b>Common Stock</b>	<b>Shares</b>		<b>% of Outstanding</b>
	<b>Preferred</b>	<b>Common</b>	
<b>Authorized</b>	20,000,000	200,000,000	
<b>Issued &amp; Outstanding</b>	-	36,434,639	72.7%
<b>Share Reservations:</b>			
Stock Options (WA exercise price \$0.96)		7,009,600	14.0%
Warrants (WA exer price \$0.58)		3,615,000	7.2%
Convertible notes (\$1.01/share)		3,078,383	6.1%
<b>Total reserved</b>		<b>13,702,983</b>	<b>27.3%</b>
<b>Total Common Outstanding and Reserved</b>	<b>-</b>	<b>50,137,622</b>	
<b>Total Available Shares</b>	<b>20,000,000</b>	<b>149,862,378</b>	

**Clean Structure & Capital Efficient**







*Developing Disruptive Therapeutics  
for the Treatment of Pancreatic Diseases*

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*Thank You!*  
*OTCQB: SNBP*

