**December 2019** 

# Innovate, Deliver and Grow





# Forward-Looking Statements Non-GAAP Financial Measures

#### **Forward-Looking Statements**

Certain statements in this presentation are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to our ability to execute on our business strategy to enhance long-term stockholder value; risks and uncertainties related to our ability to address our outstanding balance of the convertible notes due in May 2020; risk and uncertainties related to the timing, strategy, structure and success of our capital raising efforts; risks and uncertainties related to our liquidity and capital resources; risks and uncertainties related to our history of losses and variable quarterly results; risks and uncertainties related to our expected future revenues, operations and expenditures; risks and uncertainties related to our ability to identify and acquire cash flow generating assets and opportunities; risks and uncertainties related to the timing, strategy, tactics and success of the marketing and sales of PANCREAZE, including our ability to improve patient access to PANCREAZE; risks and uncertainties related to our, or our current or potential partner's, ability to successfully commercialize Qsymia, including our ability to improve patient and physician access to Qsymia; risks and uncertainties related to the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy requirements; risks and uncertainties related to the design and outcome of any clinical study required by the U.S. Food and Drug Administration ("FDA"); risks and uncertainties related to the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods; risks and uncertainties related to our ability to sell through the Qsymia retail pharmacy network and the Qsymia Advantage Program; risks and uncertainties related to our ability to successfully develop or acquire a proprietary formulation of tacrolimus; risks and uncertainties related to our ability to identify, acquire and develop new product pipeline candidates; risks and uncertainties related to our ability to demonstrate through clinical testing the quality, safety, and efficacy of our current or future investigational drug candidates or approved products; risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA/SPEDRA (avanafil) by our current or potential collaborators; risks and uncertainties related to our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with MTPC in which we do not have a commercial collaboration: risks and uncertainties related to our ability to work with FDA to significantly reduce or remove the requirements of the clinical post-approval cardiovascular outcomes trial; risks and uncertainties related to our dialog with certain concerned member states in Europe relating to the pending decentralized Marketing Authorization Application, the timing and scope of the assessment by such Concerned Member State health authorities of our Marketing Authorization Application, and ultimately the decision of such Concerned Member State health authorities whether to grant Marketing Authorization for Qsymia in such EU countries; risks and uncertainties related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; and risks and uncertainties related to the impact, if any, of changes to our Board of Directors and senior management team. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2018 as filed on February 26, 2019, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

#### **Use of Non-GAAP Financial Measures**

We supplement our condensed consolidated financial statements presented on a GAAP basis by providing additional measures which are considered non-GAAP under applicable SEC rules, such as EBITDA and Enterprise Value. We believe that the disclosure of these non-GAAP measures provides investors with additional information that reflects the basis upon which our management assesses and operates our business. These non-GAAP financial measures are not in accordance with GAAP and should not be viewed in isolation or as a substitute for GAAP net loss and are not a substitute for, or superior to, measures of financial performance performed in conformity with GAAP.

# VIVUS – an Emerging Pharmaceutical Company Focused on Unmet Medical Needs

Integrating pharmaceuticals, technology, and market access solutions to deliver superior patient outcomes



## Three Commercial-Stage Assets in Large Markets

- Qsymia a safe and effective therapy for body mass index management
- PANCREAZE a treatment for exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
- STENDRA / SPEDRA a phosphodiesterase 5 inhibitor for the treatment of erectile dysfunction



### Underpinned by a Technology Platform to Deliver Superior Outcomes

• The VIVUS Health Platform is an innovative health solution that integrates pharmaceuticals, technology, and clinical stakeholders to improve patient outcomes through increased information capture, resulting in enhanced patient access, increased adoption, and treatment durability



## High-Value, Near-Term Label Expansion and Pipeline Opportunities

- Qsymia is being evaluated in an ongoing clinical trial for the management of BMI in adolescents
- Qsymia label expansion opportunities in bariatric surgery, pre-diabetic patients, sleep apnea, and NASH<sup>1</sup>
- VI-0106 is a proprietary formulation of tacrolimus for PAH<sup>2</sup> that is Phase 2a/b ready



## Management Team with a Proven Operational Track Record

- John Amos (CEO) has 25+ years of healthcare experience as an operator, CEO, investor, board member, and history of successful deal performance
- Leadership team with extensive experience in drug development, commercial execution, and market access strategies

NASH: Non-alcoholic steatohepatitis.

# **Corporate Timeline**

#### **History**

- 1994 IPO as sexual health company
- 2 1996 FDA approved MUSE for ED
- 3 1998 Operational restructuring, FDA approved VIAGRA
- 2000 Withdrew NDA for ALIBRA
- (5) 2007 Leland Wilson named CEO, FDA approved EvaMist, sale of EvaMist to KV Pharmaceutical
- 6 2009 John Slebir named General Counsel
- 2010 Sale of MUSE to Meda
- 2012 FDA approved STENDRA and Qsymia, addition to BoD, Santosh Varghese named Head of Medical Affairs

- 9 2013 \$110M royalty financing + \$250M convertible notes
- 2013 First Manhattan launched proxy fight, 2 additions to BoD, Leland Wilson (CEO) departed, Tony Zook named CEO, Seth Fischer replaces Tony Zook as CEO
- 10 2015 Mark Oki named CFO and CAO
- 2017 Seth Fischer (CEO) departed
- 2018 Acquired PANCREAZE, John Amos named CEO
- (4) 2018 \$110M debt facility with Athyrium

# 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018

#### First 5 Quarters of 10-Quarter Turnaround

#### **Operational Accomplishments**

#### **Qsymia**

- ✓ Launched Telemedicine platform
- ✓ Initiated Direct-to-Patient model
- ✓ Reduced and simplified pricing
- Approval in South Korea
- ✓ Decentralized European submission

#### VI-0106

Defined clinical approval pathway

#### **PANCREAZE**

- ✓ Relaunched in Q1 2019 with a 10 person sales force
- Introduced co-pay card and sampling programs
- Launched the Patient Assistance program

#### STENDRA / SPEDRA

 Additional approvals in Russia and the Middle East

#### 2018 Q3 - 2019 Q3

#### **Financial Accomplishments**

- Repaid \$48.6M of senior secured debt to reduce interest cost
- ✓ First time since 1997 that VIVUS has generated recurring positive EBITDA

#### **Governance Accomplishments**

- Streamlined operations President / COO positions
- Reduced size of Board of Directors

## Restart & Return to Growth

#### **Next 5 Quarters of 10-Quarter Turnaround**

#### **Operational Goals**

#### Drive value through EBITDA generation

#### **Qsymia**

- Enhance and expand Qsymia Advantage
- Expand reimbursement, with a focus on selfinsured employers

#### VI-0106

File IND and initiate Phase 2a/b trial

#### **PANCREAZE**

- Expand contracts with major PBMs
- expanded dose range
- Offer cash pay discounts to establish market presence
- Cedar Sinai IST<sup>1</sup> in pancreatic cancer
- Partner in available countries
- Reduce working capital commitment

- Improve formulation for greater shelf life and
- STENDRA / SPEDRA

#### 2019 Q4 - 2020 Q4

#### **Financial Goals**

- O Address \$181M of convertible notes due May 2020
- Refinance \$61M of senior secured debt

#### **Corporate Development Goals**

 Opportunistically assess value–accretive M&A

#### **Return to Growth**

#### **Operational Goals**

#### **Qsymia**

- Target GI physicians
- Political lobbying
- Introduce subscription model
- Monetize ex-U.S. territories

#### **Pipeline and Label Expansion**

- Qsymia label expansion in adolescent obesity, pre-diabetic patients, sleep apnea, and NASH
- O Develop VI-0106 for PAH

#### **PANCREAZE**

- Enhance and expand PANCREAZE Advantage Program
- Long term care pharmacies

#### **VIVUS Health Platform**

- Directed trial program
- Remote patient monitoring
- Improve medical loss ratio
- Incorporate additional products

#### Growth

#### **Financial Goals**

- O De-lever balance sheet with cash flow
- Optimize capital structure

#### **Corporate Development Goals**

O Pursue cash-flow positive acquisitions through capital efficient deals

# Experienced Management Team

The right team is in place to complete the turnaround and return VIVUS to growth

#### Name & Position

#### **Prior Experience**



**John Amos** Chief Executive Officer & Director











**MCKESSON** 



Santosh Varghese, M.D. Chief Medical Officer











**Mark Oki** Chief Financial Officer & Chief Accounting Officer











John Slebir, Esq. General Counsel & SVP, Business Development





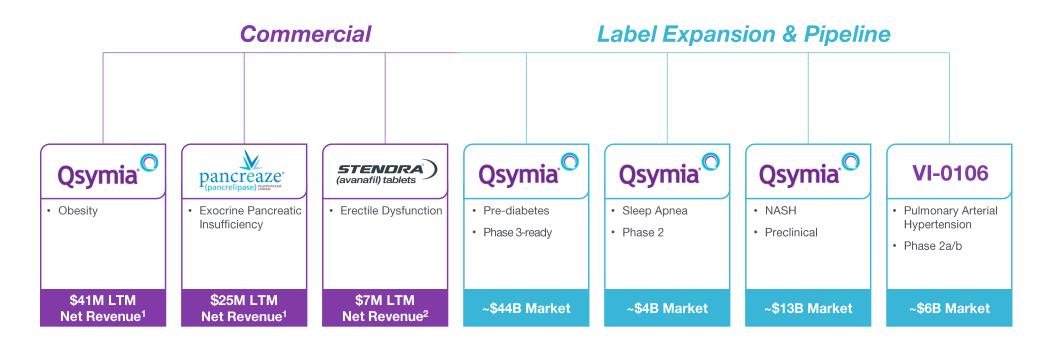


**Deborah Larsen** Chief Strategy Officer





## **Product Portfolio Overview**



Source: CDC, American Sleep Apnea Association, NIH, Medgaget market data.

Note: LTM values as of September 30, 2019. (1) Includes license and royalty revenue.

(2) Includes royalty and supply revenue.

## The VIVUS Health Platform

We have created a differentiated platform centered around our proprietary therapeutics to engage physicians, improve access, and empower patients to deliver superior outcomes

## **Physician Engagement**

#### **Patient Access**

#### **Patient Experience**

#### **Delivering Early Results**

30% reduction in out-of-pocket expenses for Qsymia

\$52.32 average out-of-pocket expenses for PANCREAZE Advantage members

273% increase QoQ in Qsymia Direct-to-Patient TRx in Q3 2019 92% fulfillment rate for Qsymia Advantage prescriptions



#### **Remote Patient Monitoring**

Passive data collection from Bluetooth devices empowers physicians to better manage patient outcomes



#### **Physician Partnership**

Unique partnership model that incentivizes physicians by allowing them to participate in economics



#### **Sampling Programs**

Physician sampling programs to broaden exposure at key call points



#### **Co-Pay Cards**

Reducing out-of-pocket expenses so more patients can get the treatment they need



#### **Patient Assistance**

Medications at no cost for eligible patients unable to pay for their prescriptions



#### **Telemedicine**

Providing a flexible channel for greater access to healthcare services



#### **Direct-to-Patient Delivery**

Greater convenience, with medications shipped directly to the patient's door



#### **Patient Data Engagement**

Digital tools that empower physicians and patients to achieve superior clinical outcomes



#### **VIVUS Health Store**

Monthly savings on products to support patients' needs

# **Marketed Products**



# Portfolio of Three Commercial Stage Assets in Large Markets







Approval Date	July 2012	April 2010	April 2012
Indication	Obesity in Adult Patients	Exocrine Pancreatic Insufficiency	Erectile Dysfunction
Description	Proprietary once-daily, extended- release formulation of low doses of phentermine and topiramate	Combination of porcine-derived lipases, proteases, and amylases	Oral PDE5 inhibitor
Mechanism of Action	Quick-release phentermine starts working immediately to reduce appetite, while extended-release topiramate works throughout the day to help patients feel full	Acts as a replacement for the missing digestive enzymes produced by the pancreas to help patients digest normally	Triggers relaxation of arterial smooth muscle, leading to arterial dilation, venous constriction, and erection

# **Q**symia

# Multiple Factors Held Qsymia from Meeting Commercial Expectations

Despite Qsymia's superior clinical profile, the prior VIVUS management team did not develop a commercial strategy to achieve its potential in the evolving obesity market

#### Limited Reimbursement

- Limited reimbursement of prescriptions
- Largely designated Tier 2 or Tier 3 by commercial payors, with high out-of-pocket expenses
- Reimbursement was largely restricted to employer-sponsored insurance plans

#### High Out-of-Pocket Costs

- Out-of-pocket costs accounted for a significant portion of the total amount paid for Qsymia
- Significant increase in out-ofpocket expenses with higher doses
- Portion of potential patients opted for generic phentermine due to price differential

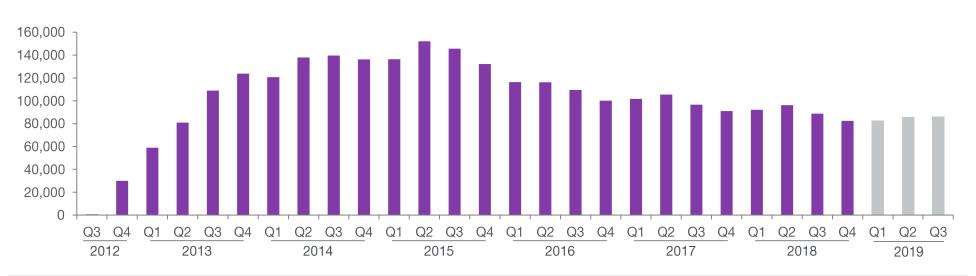
#### Free Trial Offer

- Attempted to compensate for limited reimbursement with a 15day free trial program
- ~50% of patients did not continue therapy beyond the free trial
- ~30 days of treatment at a therapeutic dose are required to demonstrate clinical results

#### Low Fulfillment

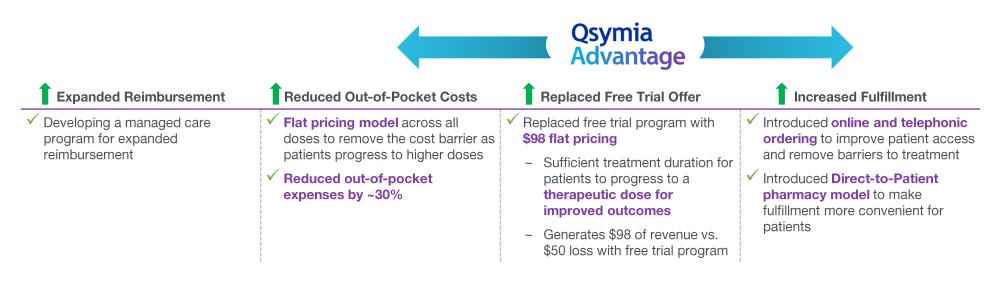
- Fulfillment rates for prescriptions written by physicians were limited by:
  - Out-of-pocket costs
  - Stocking issues frequently resulted in loss of market share to generic phentermine
  - This occurred despite notable fluctuations in weight associated with generic phentermine

#### Quarterly Qsymia TRx Volume

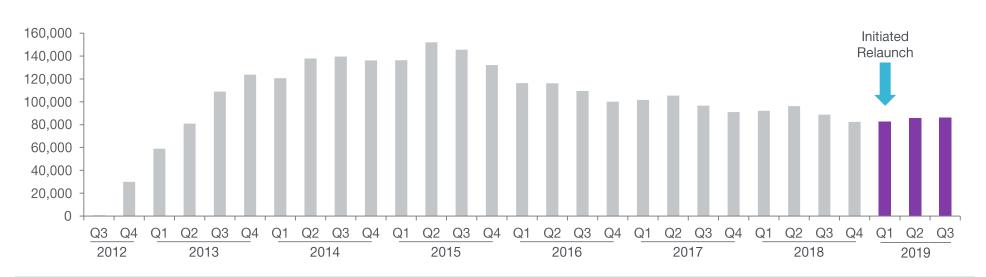


# The Strategic Relaunch of Qsymia has Gained Momentum

As part of our strategic reset, we have implemented multiple solutions to course-correct Qsymia



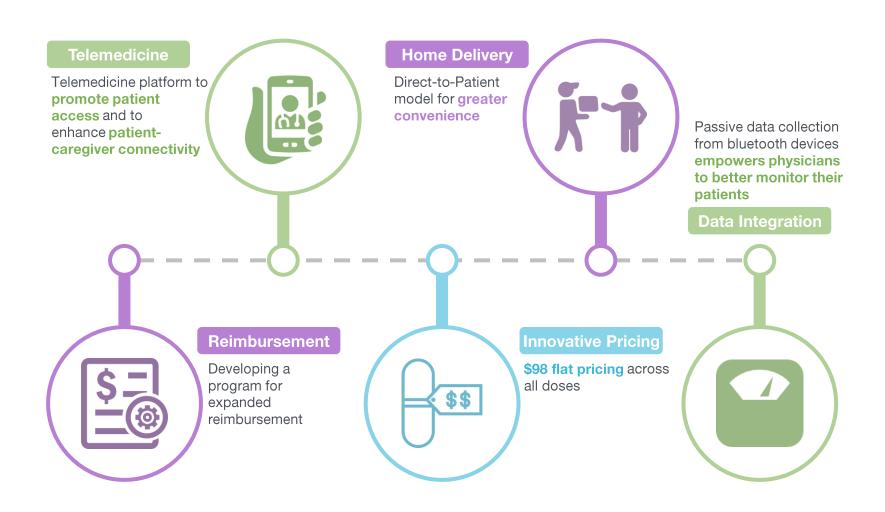
#### Quarterly Qsymia TRx Volume





# Engaging and Empowering Patients to Achieve Superior Outcomes with the Qsymia Advantage Program

We've made it easier for patients to get Qsymia, manage their plan and achieve their weight-loss goals





# **PANCREAZE**

# Commercial Neglect Led to Underrepresentation in the Market

#### **Third to Market**

- Although PERT products had been used for a number of years, the FDA required formal approval in 1991
- PANCREAZE was the third PERT to receive FDA approval in April 2010, following Creon in May 2009 and Zenpep in August 2009

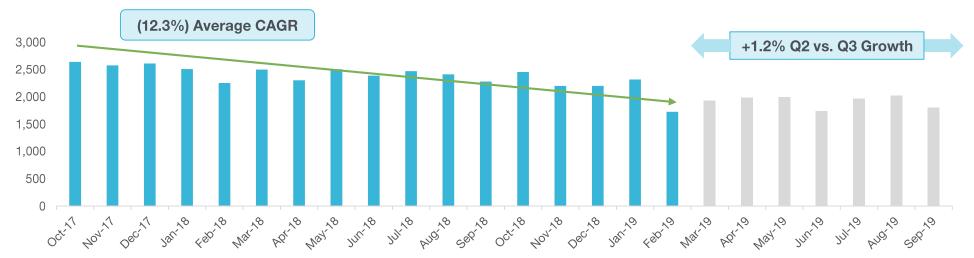
#### Lack of Sales Infrastructure

- Janssen completely cut sales, marketing, and commercial infrastructure for PANCREAZE in 2012
  - Small patient assistance program remained
  - Absence of sales efforts saw
     PANCREAZE market share decline

#### **Disjointed Transition**

- Changeover from JnJ NDC code to VIVUS NDC code temporarily caused a drop in TRx volume due to issues with claims reimbursement
- Inefficient transfer of several key national accounts

#### **PANCREAZE Historic Monthly TRx Volume**



2019 data is through September 20, 2019.



# Commercial Traction Following Strategic Relaunch

Our commercial repositioning has returned PANCREAZE to quarter-over-quarter growth for the first time in the last 14 quarters



#### **Focus on Relaunch**

- Relaunched the brand in February 2019 following transitionary period from Janssen
- Prioritizing supply chain improvement and working capital management
- Working to move PANCREAZE back into the view of the medical community
  - Supporting ongoing clinical trials at Cedar Sinai in pancreatic cancer



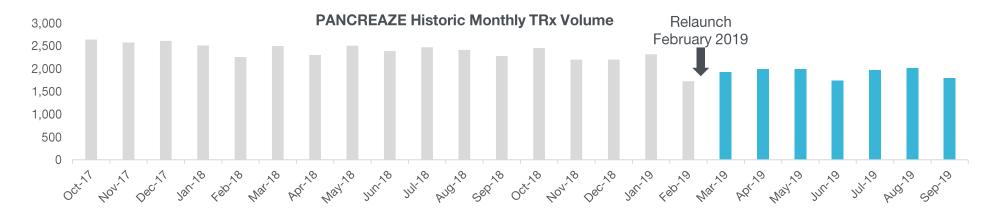
# Re-Establishing Sales Efforts

- Added 10 outside sales reps as a part of the relaunch
- Began a white-space campaign to address un-engaged portions of the market
- Expanded promotional efforts with a broader sampling program and options for inside sales reps
- Revised sales aid with a new patient profile for GI Doctors and simplified dosing materials



# Strengthening Payor Relationships

 Negotiating better formulary placement with select PBMs to drive TRx volume



# Enhanced Patient Access and Experience with the PANCREAZE Advantage Program

Near-term promotional efforts to engage with patients, payors and prescribers

Patient and Payment Assistance





- Patient assistance programs to help navigate the reimbursement process
- Co-pay cards to lower out-of-pocket costs for eligible patients
- Cash discount program to aid in making PANCREAZE an affordable alternative

Patient Support Program







 Up to \$100 of credit on VIVUS Health Online store to purchase nutraceuticals and nutritional supplements

Patient and Physician Educational Materials







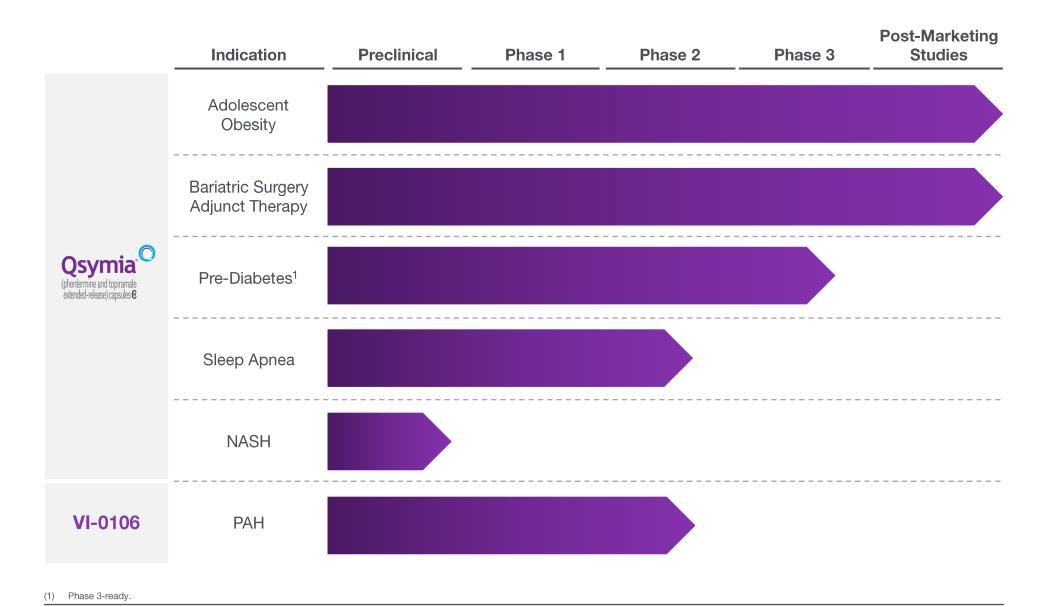


 Mobile application that details dosing data and equivalents to aid patients and physicians making the switch to PANCREAZE

# Pipeline and Label Expansion Opportunities



# Multiple Development Programs to Expand Commercial Franchise

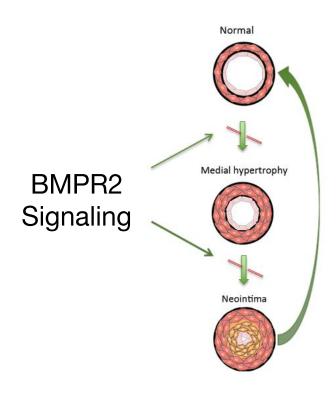




# VI-0106 is a Potential Disease Modifying Therapy for PAH

We are developing VI-0106, an extended release formulation of Tacrolimus, for the treatment of PAH

- Bone Morphogenic Protein Receptor 2 (BMPR2) signaling inhibits vascular smooth muscle proliferation
- Reduced BMPR2 expression, including loss-of-function mutations in BMPR2, is prevalent in PAH patients, and may contribute to smooth muscle proliferation
- Low doses of tacrolimus have been shown to restore BMPR2 signaling
- Low dose tacrolimus reverses neointimal hypertrophy in animal models of PAH
- Enhancement of BMPR2 signaling with tacrolimus may address a fundamental cause of PAH
- Not mutation dependent



# VI-0106 has Demonstrated Promising Clinical Results

#### **Study Description**

**Purpose:** Evaluate the feasibility, safety, and tolerability of 3 different exposure levels of tacrolimus

#### Design:

- Double-blind, randomized, placebo-controlled study of 23 subjects with stable PAH
- Subjects were randomized to target trough blood levels of tacrolimus
- Treatment period of 14 weeks

#### Results

- All target exposure levels of tacrolimus were well tolerated, with no drug-related serious adverse events
- Target exposure levels were generally achieved within the first 1-2 weeks of treatment and maintained throughout the study
- Meaningful efficacy conclusions were impaired by the small sample size, short treatment duration, and high baseline function of the study population

# Compassionate Use Study

**TransformPAH** 

Phase 2a Study

**Purpose:** Evaluate tacrolimus in 3 end-stage PAH patients that did not meet the entry criteria for the TransformPAH study

#### Design:

- Open label treatment for 3 end-stage PAH patients
- Treatment with tacrolimus targeted to trough blood levels of 1.5 to 2.5 ng/mL
- Formal study follow-up for 1 year, survival and hospitalizations tracked for up to 6 years



- Treatment with tacrolimus had a significant impact on clinical outcomes
- Dramatically reduced rate of hospitalizations
- Functional class improvements observed

We plan to file an IND for a Phase 2a/b clinical study evaluating VI-0106 for the treatment of PAH in 1H 2020



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Integrating pharmaceuticals, technology, and market access solutions to deliver superior patient outcomes



Three Commercial-Stage Assets in Large Markets



Underpinned by a Technology Platform to Deliver Superior Outcomes



High-Value, Near-Term Label Expansion and Pipeline Opportunities



Management Team with a Proven Operational Track Record