



## Corporate presentation

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NASDAQ: STSA | November 10, 2021

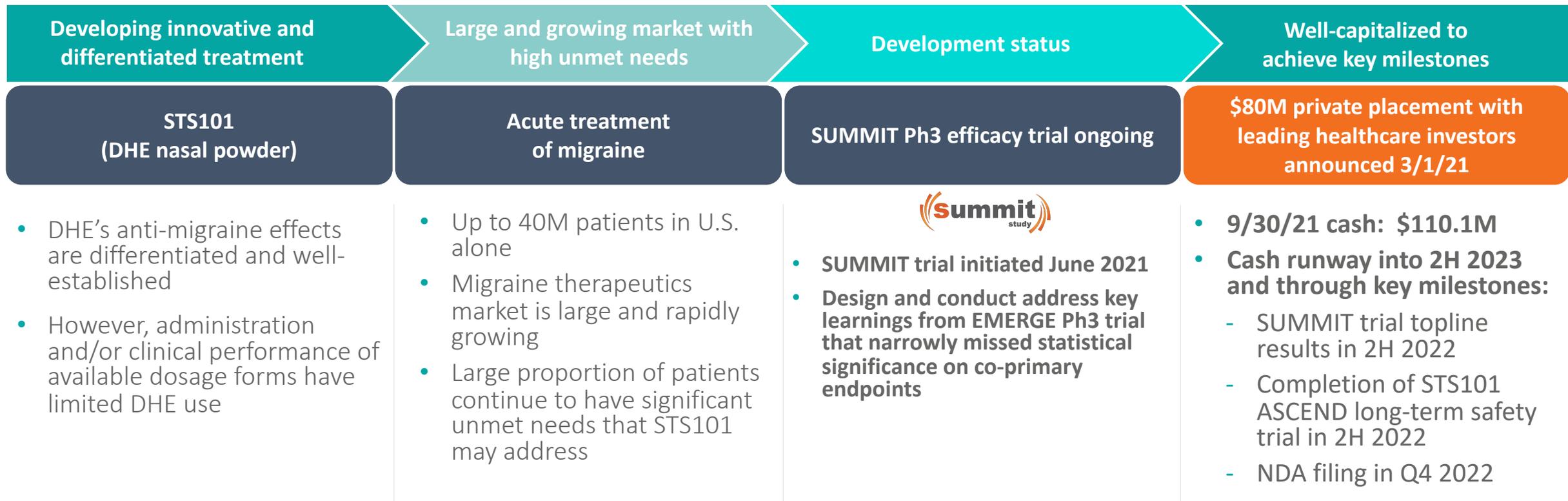


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This Presentation contains forward-looking statements concerning the business, operations and financial performance and condition of Satsuma Pharmaceuticals, Inc. (the “Company”), as well as the Company’s plans, objectives and expectations for its business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about the Company’s expectations regarding the potential safety and efficacy of STS101; the Company’s clinical and regulatory development plans; the Company’s expectations with regard to the ASCEND and SUMMIT trials; the Company’s expectations regarding the potential market size and size of the potential patient populations for STS101, if approved for commercial use; the Company’s commercialization, marketing and manufacturing plans and expectations; the pricing and reimbursement of STS101, if approved; the implementation of the Company’s business model and strategic plans for its business and STS101; the scope of protection the Company is able to establish and maintain for intellectual property rights covering STS101, including the projected terms of patent protection; estimates of the Company’s expenses, future revenue, capital requirements, its need for additional financing and its ability to obtain additional capital; the Company’s future financial performance; and developments and projections relating to the Company’s competitors and the Company’s industry, including competing therapies and procedures. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. The Company’s actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to, risks detailed in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time. In particular, the following factors, among others, could cause results to differ materially from those expressed or implied by such forward-looking statements: the accuracy of the Company’s estimates relating to its ability to initiate and/or complete clinical trials; the Company’s ability to demonstrate sufficient evidence of efficacy and safety in its clinical trials of STS101; the Company’s ability to select suitable dosing regimens; the results of preclinical and clinical studies may not be predictive of future results; the unpredictability of the regulatory process; regulatory developments in the United States and foreign countries; the costs of clinical trials may exceed expectations; the Company’s ability to raise additional capital; and the risk that costs of clinical trials and preclinical activities will exceed expectations. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

This Presentation discusses STS101, a product candidate that is under clinical study, and which has not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of STS101 for the therapeutic use for which STS101 is being studied.

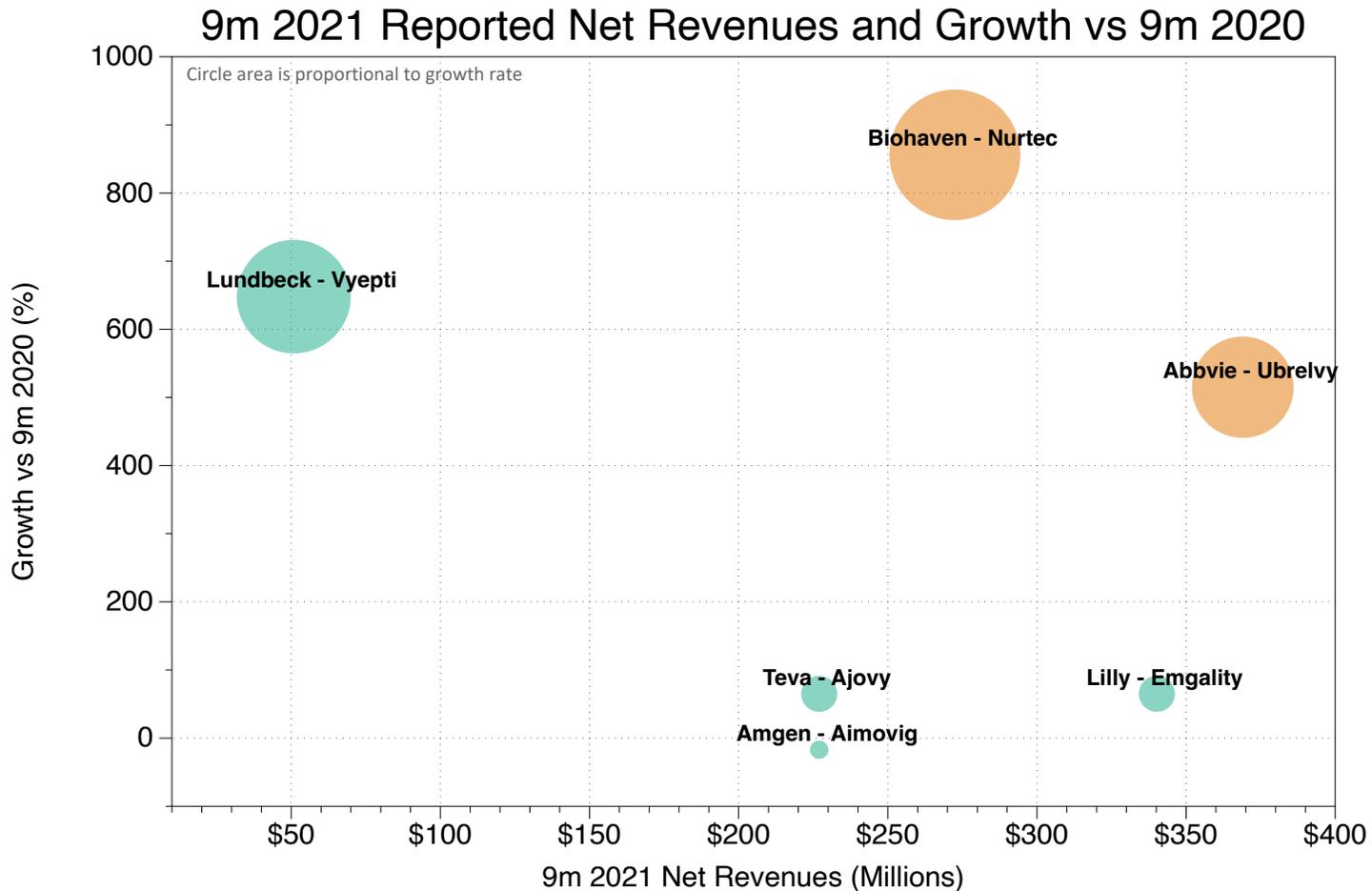
# Summary



<p><b>STS101</b></p> 	<ul style="list-style-type: none"> <li><b>Proprietary, advanced formulation technology and improved, 2<sup>nd</sup>-generation delivery device</b></li> <li><b>Broad and long-lived IP estate with expected U.S. patent protection through late 2039</b></li> </ul>	<ul style="list-style-type: none"> <li><b>Team with strong track record of execution</b></li> <li><b>Significant value creation opportunity</b></li> </ul>
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# Migraine market is large, growing and significant unmet needs remain

## Sales of new preventive and acute migraine treatments are growing rapidly



**Commercial success of new migraine products underscores large market opportunity, significant unmet needs and favorable dynamics**

- Six new preventive and acute products targeting CGRP generated nearly \$1.5B in reported net revenues in first 9 months of 2021, representing a 132% increase versus the comparable period in 2020
- Introduction of new acute therapies has expanded overall market; prescriptions for other acute therapies, i.e., triptans, have increased

	9m 2021 Net Sales	Growth from prior year
New preventives	\$845M	37%
New acute therapies*	\$641M	625%

\*Nurtec approved by FDA for prevention indication in late May 2021 5

# Dihydroergotamine (DHE) is highly effective but shortcomings of injectable and liquid nasal spray dosage forms have limited use



- Long recommended as a first-line option for the acute treatment of migraine
- Unique and multi-faceted MoA
- Significant advantages over triptans and new acute treatments
- Broad clinical utility, including for difficult-to-treat migraines & triptan “low responders”
- Could address many shortcomings of triptans and gepants if available in an easy-to-use and consistently effective dosage form

Clinical attribute	Triptans	DHE
<b>Long treatment window with minimal attenuation of effect when administered late in course of attack<sup>1</sup></b> Opportunity for early treatment possible in only ~50% of attacks <sup>2</sup>	×	✓
<b>Low risk of 24+ hr headache recurrence<sup>3</sup></b> Recurrence in up to 45% of triptan-treated attacks <sup>3</sup>	×	✓
<b>Effective in migraine with allodynia<sup>4</sup></b> Present in majority of attacks (53-79%) <sup>5</sup>	×	✓
<b>Effective in triptan non-responders<sup>6</sup></b> ~40% of patients don't respond* to oral triptans; <sup>7</sup> ~50% of triptan non-responders shown to respond to DHE <sup>6</sup>	×	✓
<b>Low risk of medication overuse headache<sup>8</sup></b>	×	✓

Sources:

1. Tepper, Mayo Clin Proc 2011
2. Valade, Cephalalgia 2009
3. Winner, Arch Neurology 1996
4. Tepper, Headache 2012

5. Lipton, Headache 2017
6. Fisher, Curr Med Res Opin 2007
7. Ferrari, Cephalalgia 2002
8. Saper, Headache 2006

\*40% based on pain relief at 2 hours from administration; up to 80% do not achieve sustained freedom from pain

# DHE products have long been available and demonstrate favorable efficacy with adequate drug exposure--but have been burdened by administration challenges

## DHE for Injection (IV, IM, SC)

Marketed since 1946



### Gold standard treatment for severe / refractory migraine

- Injections are painful and burdensome
- Patients prefer non-injectables
- Common side effects of IV-delivery include nausea and vomiting
- Requires healthcare provider involvement (IV and frequently IM)

## DHE liquid nasal sprays (Migranal, INP104/Trudhesa)

First approved in 1997



### Inconsistent and unreliable clinical performance and sub-optimal therapeutic response for many patients

- Low, slow, and highly variable absorption
- Involved administration procedure and inherent nature of liquid spray formulation result in high dose variability
  - Require assembly & priming
  - 4 sprays administered over 15 minutes
- INP104/Trudhesa (recently approved) is at best incremental improvement over Migranal

## MAP0004 Inhaled, multi-dose, breath-actuated DHE

Discontinued after 3 CRLs (2012-2015) for CMC



### Ph3 data underscore DHE differentiation & benefits

- Introduction was highly anticipated by headache physicians
- Developer MAP Pharmaceuticals acquired by Allergan for \$958M

MAP0004 also known by the brand names Semprana and Levadex.

There is an unmet need for a patient-friendly, self-administered, non-injected DHE product that delivers rapid, durable, and robust efficacy

## OUR SOLUTION: STS101 (DHE nasal powder)

Proprietary 2nd generation nasal delivery device & dry-powder formulation technologies



### Drug-Device Combination

- Differentiated and injectable-like PK
- Quick and intuitive administration
- Anti-migraine effects and favorable safety and tolerability observed to date in our clinical trials



### Single-use, 2<sup>nd</sup> generation nasal delivery device

- Convenient and patient-friendly; no assembly or priming required
- Administration of a full-dose within seconds
- Pocket-sized, smaller than available DHE liquid nasal spray devices; discreet and disposable



### Proprietary mucoadhesive nasal powder formulation

Incorporates drug carrier and engineered drug particle technologies that facilitate rapid drug absorption and optimal PK profile

# Easy and intuitive administration – a full dose within seconds



1

FOLD  
OFF TAB



2

INSERT  
IN NOSTRIL



3

SQUEEZE  
TO DELIVER  
(REPEAT 3X)

## Our development strategy positions STS101 for commercial success

### Develop STS101 as a highly differentiated anti-migraine therapeutic suitable for broad use

- ✓ Simple and easy to use with attractive form factor
- ✓ Unique and optimized PK profile--more drug on board faster than possible with liquid nasal sprays—expected to translate to robust and differentiated efficacy profile
- ✓ Favorable safety and tolerability (as observed to date in >700 subjects who have treated >5,000 migraine attacks with STS101 5.2 mg)
- ✓ Generate compelling and highest quality clinical evidence in large, randomized, controlled trial (ongoing SUMMIT trial)
  - Differentiated and efficacy claims in label that are unique to STS101
  - **First and only DHE product with label claims on modern efficacy endpoints (Pain and MBS freedom at 2h) accepted and endorsed by FDA and International Headache Society**

#### Rapid Adoption

- Prescribers
- Patients



#### Acceptance & Reimbursement

- Formulary & Reimbursement Coverage
- Medical Guideline Inclusion



# STS101 5.2 mg achieved target PK profile in 2021 Ph1 trial



Rapidly achieved and sustained target plasma concentrations with low variability

Expect PK profile to translate to

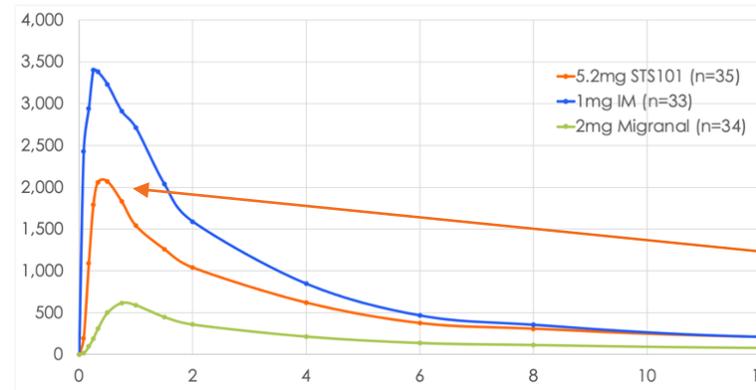
- Fast onset
- Robust efficacy by 2 hours and beyond
- Sustained efficacy with low recurrence

Favorable safety & tolerability

- STS101 5.2 mg continues to demonstrate low AE rates
- Incrementally higher AE rates observed with STS101 dose strengths > 5.2 mg (e.g., nasal congestion, nausea and vomiting)

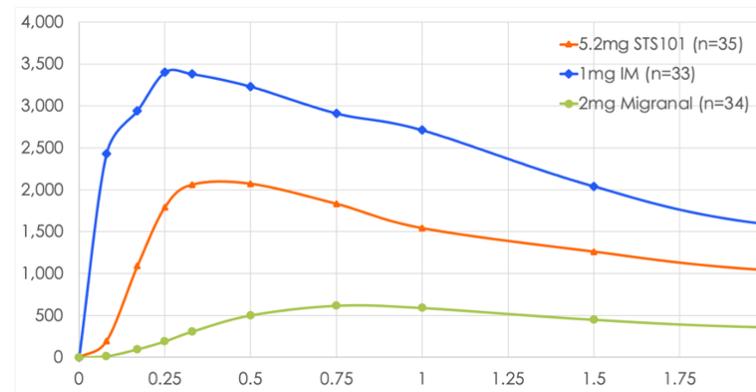
Adverse Event	5.2 mg STS101	IM DHE	Migranal
Safety Population (n)	35	34	34
At least 1 treatment related AE	5 (14%)	10 (29%)	4 (12%)
Nasal congestion	2 (6%)		1 (3%)
Nasal discomfort	1 (3%)		
Nausea	1 (3%)	3 (9%)	
Headache		2 (6%)	
Dizziness	1 (3%)		
Emesis		1 (3%)	

## 2021 Ph1 PK study with 2<sup>nd</sup> generation delivery device Mean DHE plasma concentration (pg/mL)



- Early peak is key for efficacy at 2h
- C<sub>max</sub> > ~2500 pg/ml results in higher rate of systemic side effects

### Time after dosing (0-12 hours)



### Time after dosing (0-2 hours)

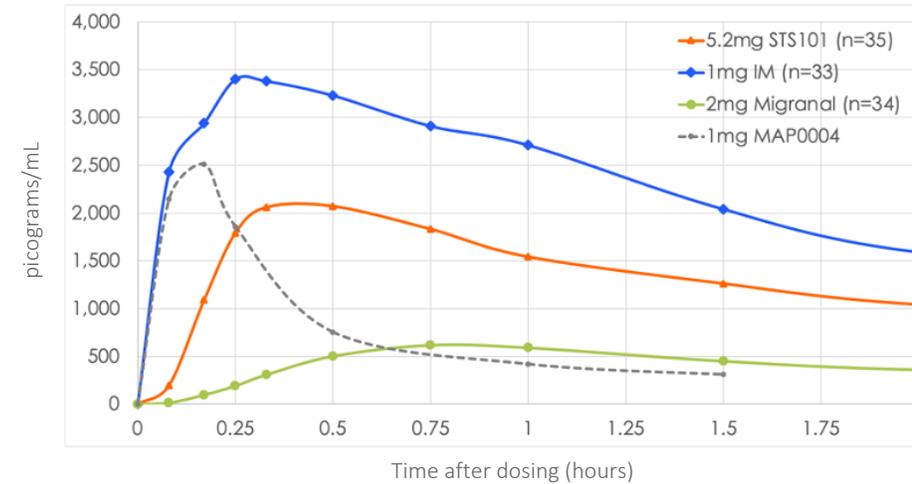
Source: STS101-006 Phase 1 Study Preliminary Results – June 2021

# STS101 5.2 mg achieved target PK profile in 2021 Ph1 trial



- STS101 achieved ~2.5x total drug exposure ( $AUC_{0-inf}$ ) vs. MAP0004 pulmonary-route DHE, with greater exposure achieved by 30 minutes and all times thereafter
- More rapid and higher drug exposure achieved with lower variability versus liquid nasal spray DHE products
- STS101 PK profile similar to IM DHE and MAP0004, which have consistently demonstrated robust efficacy by 2 hours post-treatment in randomized, controlled clinical trials

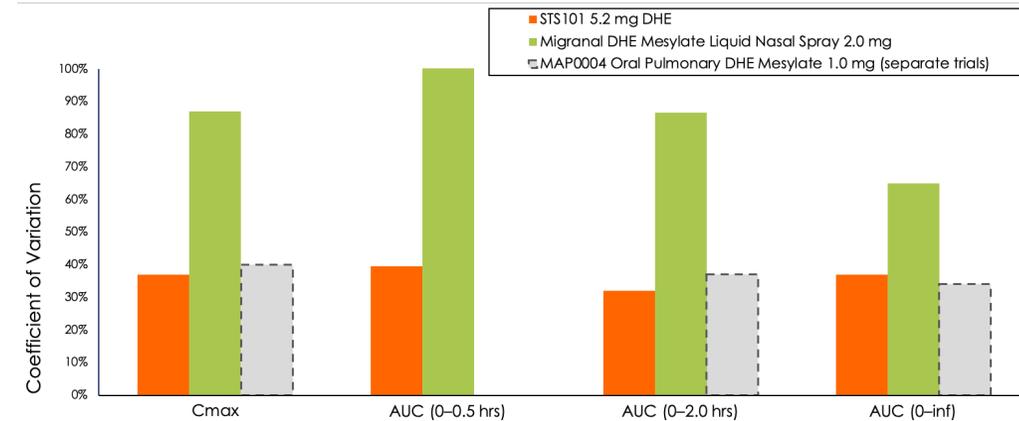
## Mean DHE plasma concentration of STS101 versus other non-injectable DHE products



**MAP0004** had robust 2h efficacy in large RCT, but lower efficacy at later time points

**Migranal** has marginal and inconsistent 2h efficacy in RCTs

## STS101 PK variability less than DHE liquid nasal spray and comparable to MAP0004



Source: Kellerman et al., J Aerosol Pulm Drug Deliv 2013; STS101-006 Phase 1 Study Preliminary Results – June 2021

Note: As the data presented above is based on a cross-trial comparison and not a head-to-head clinical trial, such data may not be directly comparable due to differences in study protocols, conditions and patient populations. Accordingly, cross-trial comparisons may not be reliable predictors of the relative efficacy or other benefits of STS101 compared to other product candidates that may be approved or that are or were in development for the acute treatment of migraine.

# ASCEND Phase 3 open-label, long-term safety trial is ongoing

- >290 subjects enrolled; migraine attacks treated on a PRN basis with STS101 5.2 mg
- >5,000 migraine attacks treated, ~48% of which had severe pain at time of treatment<sup>1</sup>
- Favorable safety and tolerability observed<sup>2</sup>

Adverse events reported by >2% of subjects	N (%) of subjects reporting AE at least once (273 subjects)	% of attacks with AE (4,247 attacks)
Nasal discomfort	39 (13.9)	2.1
Dysgeusia	21 (7.7)	2.8
Nasal congestion	17 (6.2)	1.1
Nausea	16 (5.9)	0.4
Rhinorrhea	12 (4.4)	0.4
Vomiting	10 (3.7)	0.2
Epistaxis	7 (2.6)	0.2

- No Serious Adverse Events related to STS101

- **Observed anti-migraine activity<sup>3</sup>:** Subjects report pain freedom at 2 hours post-treatment in ~30% of attacks, with low utilization of second STS101 dose (<20% of attacks) or rescue medication (<5%)

1. Severe pain at time of treatment is the key predictor of lack of response at 2 hours, as migraine pain is less responsive to treatment when it has progressed to severe pain (Diener et al., Neurology 2004; Diener et al., Cephalalgia 2007; Lombard et al., Headache 2020)
2. Safety and tolerability results based on June 30, 2021 preliminary analysis of ASCEND results
3. Preliminary results

# SUMMIT Phase 3 efficacy trial ongoing

Top-line data expected 2H 2022

## SUMMIT trial design

To qualify, patients must have experienced in each of the prior 3 months:

- $\geq 2$  and  $\leq 8$  migraines
- $< 15$  days headache days

- Designed per published FDA guidance for developing acute treatment of migraine drugs (Feb 2018)
- FDA agreed in principle with SUMMIT design and that a single efficacy study could be sufficient to support an NDA

Screening period



Treatment of single migraine attack within 56 days of randomization

(n≈700)



(n≈700)



## Endpoints & powering

- **Co-primary: Freedom from pain and most-bothersome symptom** (photophobia, phonophobia, or nausea) at 2 hours post-treatment
- Multiple secondary endpoints and prospective analyses of subgroups to potentially enhance the differentiated clinical profile of STS101

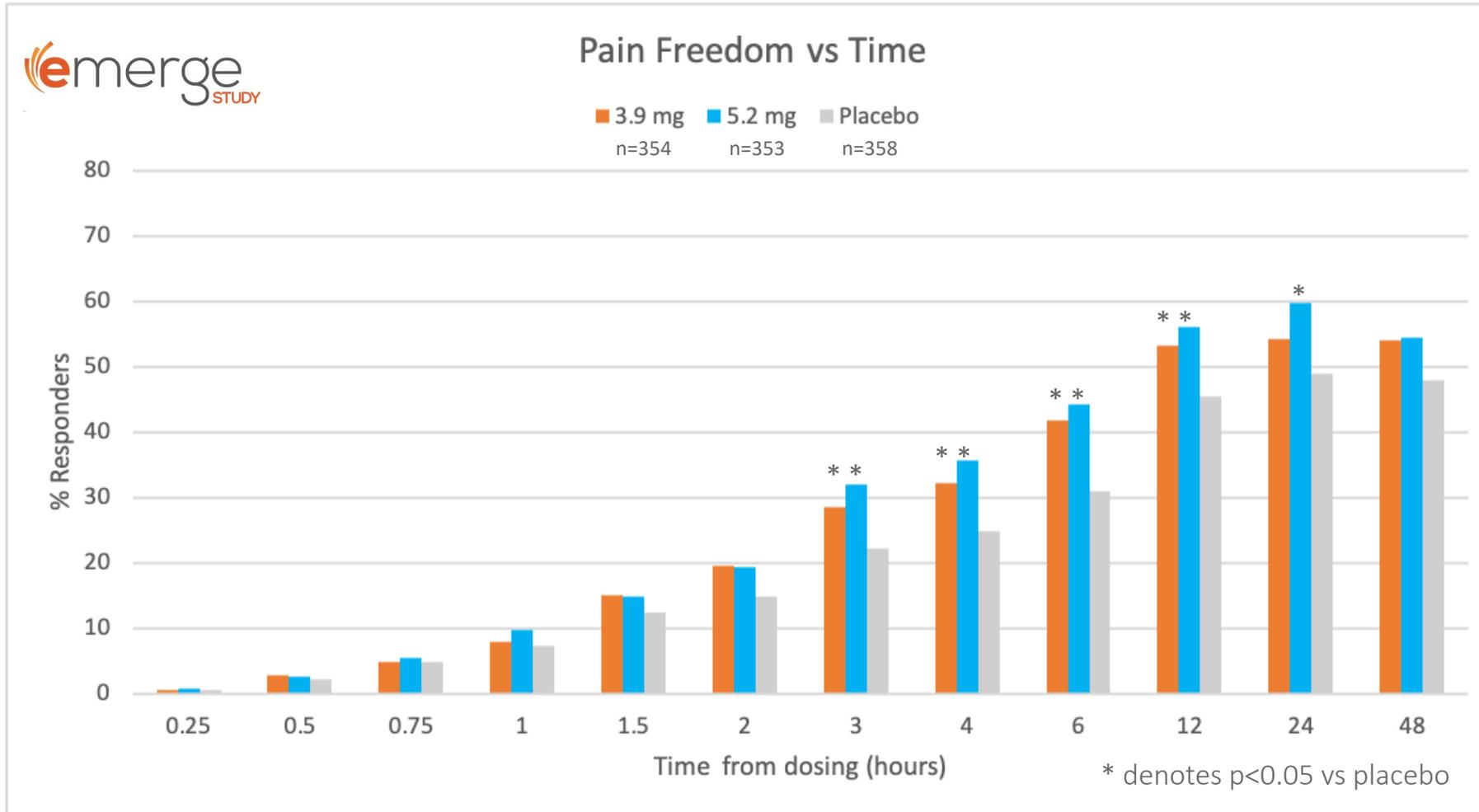
### Secondary endpoints

- Sustained pain freedom (at 24h and 48h)
- Rescue medication usage
- Pain relief
- Avoidance of relapse
- Functional and quality-of-life endpoints
- Patient global impression

### Powering

- **Freedom from pain at 2h: 99% power** to detect 10% therapeutic gain with STS101 response rate = 25%
- **Freedom from MBS at 2h: 95% power** to detect 10% therapeutic gain with STS101 response rate = 45%

# Ongoing SUMMIT Ph3 efficacy trial incorporates “lessons learned” from previous EMERGE Ph3 trial, which narrowly missed significance on co-primary endpoints (at 2h)



**STS101 5.2 mg** was numerically superior to Placebo at all time points and to STS101 3.9 mg at 9 of 12 time points

Difference vs Placebo was significant at 3 hours (p<0.05) and all time points thereafter through 24 hours

EMERGE Study Topline Data September 2020; mITT Population

Subjects with missing data at a time point imputed as nonresponders

# SUMMIT trial addresses reasons for near-miss on co-primary endpoints in EMERGE trial

## 1. STS101 under-delivery

- Improve subject training and instructions for use
- 2<sup>nd</sup> generation STS101 delivery device with minor changes
- Increased mean delivered dose by ~30% with significantly decreased variability

## 2. Early eDiary data entry

- Adjust eDiary entries to align with nominal time points

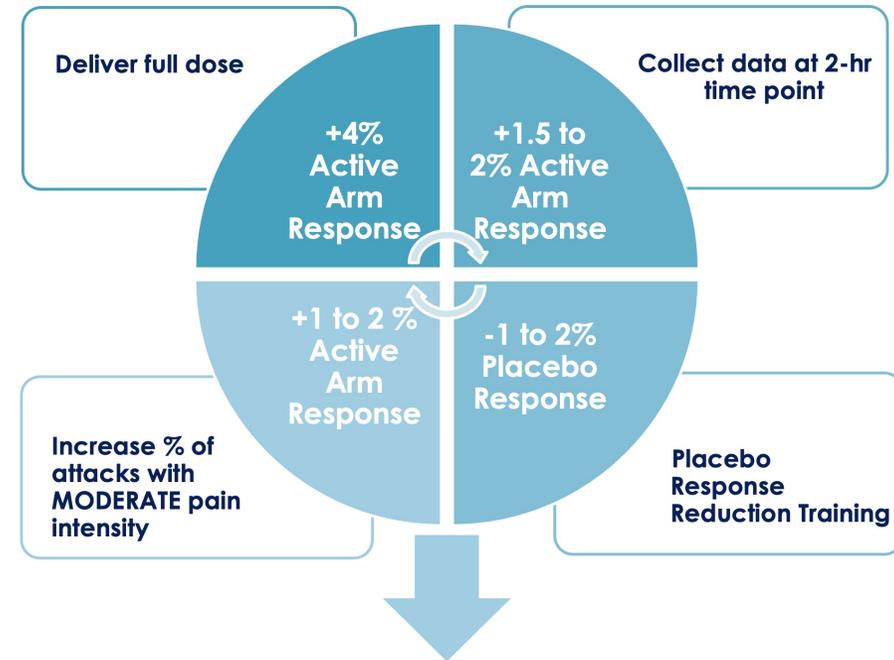
## 3. High proportions of severe/difficult-to-treat attacks

- Instruct subjects to treat qualifying migraines as soon as pain intensity reaches “moderate”
- Adjust screening procedures

## 4. High placebo response rate given severity of treated attacks

- Placebo Response Reduction training of sites and subjects
- 2-arm study will reduce expectation of receiving active vs EMERGE (3-arms: 2 active + placebo)

## Potential impact of changes on PF at 2h in SUMMIT



Estimated Response Rates (PF@2h)*	
STS101	Placebo
23-28%	12-15%

In addition, larger sample size of ~700/arm increases statistical power

\*Values are hypothetical, based on our internal modeling and may not accurately predict clinical trial results

# Sensitivity analyses underscore that SUMMIT trial has high likelihood of success

	STS101 5.2 mg	Placebo	p-value
<b>EMERGE trial (actual)</b>			
n (mITT population)	353	358	
2h PF (%)	19.3	14.8	0.11
<b>SUMMIT trial</b>			
n (nITT population)	650	650	
2h Pain Free (%) with same effect size as EMERGE	19.3	14.8	<b>0.032</b>
with eDiary entry times adjusted	22.4	16.6	<b>0.008</b>
with only +2 percentage point increase in active arm response rate due to improved delivery	24.4	16.6	<b>0.0004</b>
with % of severe pain attacks reduced from 50% to 40%	25.5	16.7	<b>0.00009</b>
with lower placebo response rate	25.5	15.0	<b>0.000003</b>

← Even with same effect size as in EMERGE, i.e., no improvement, the increase in SUMMIT sample size alone achieves p<0.05

↓ Increases in effect size resulting from adjustments to trial design, conduct and improved delivery should further reduce p-value

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## Key take-aways

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### STS101 5.2 mg

- ✓ Unique and optimized PK profile should translate to robust efficacy and favorable tolerability
- ✓ Anti-migraine activity demonstrated at 2 hours
  - Numerical superiority observed in EMERGE Ph3 for both pain freedom and freedom from MBS endpoints
  - ~30% pain freedom at 2 hours to date in open-label ASCEND Ph3, with over 5,000 migraine attacks treated
- ✓ Low AE rates and favorable safety and tolerability in all clinical trials to date
  - ~700 subjects have self-administered STS101 5.2 mg to treat more than 5,300 migraine attacks
- ✓ SUMMIT Ph3 efficacy trial is ongoing and incorporates key learnings from EMERGE trial
- ✓ Highly-differentiated product profile positioned to be best-in-class

	STS101 development milestones
Q2 2021	✓ Complete Phase 1 safety and pharmacokinetic study with STS101 5.2 mg and two higher dose strengths; select dose strength for Phase 3
Mid-2021	✓ Initiate new STS101 SUMMIT Phase 3 efficacy trial
2H 2022	Read out topline results from SUMMIT trial
2H 2022	Complete STS101 ASCEND Phase 3 long-term safety trial
Q4 2022	File STS101 NDA

Cash runway into 2H 2023 and through key milestones

## Significant long-term barriers to competitive entry / generics

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### **Broad IP estate reflects innovative nature of STS101 and our drug delivery technology**

More than sixty issued and pending U.S. and foreign patents covering formulations, dosages, devices, and methods of treatment

- **United States:** Ten issued U.S. patents with estimated last expiration in December 2039
- **Ex-U.S.:** 13 issued and allowed patents, and we expect issued and pending STS101 patents to have similar lives as in the U.S.

### **Additional competitive barriers**

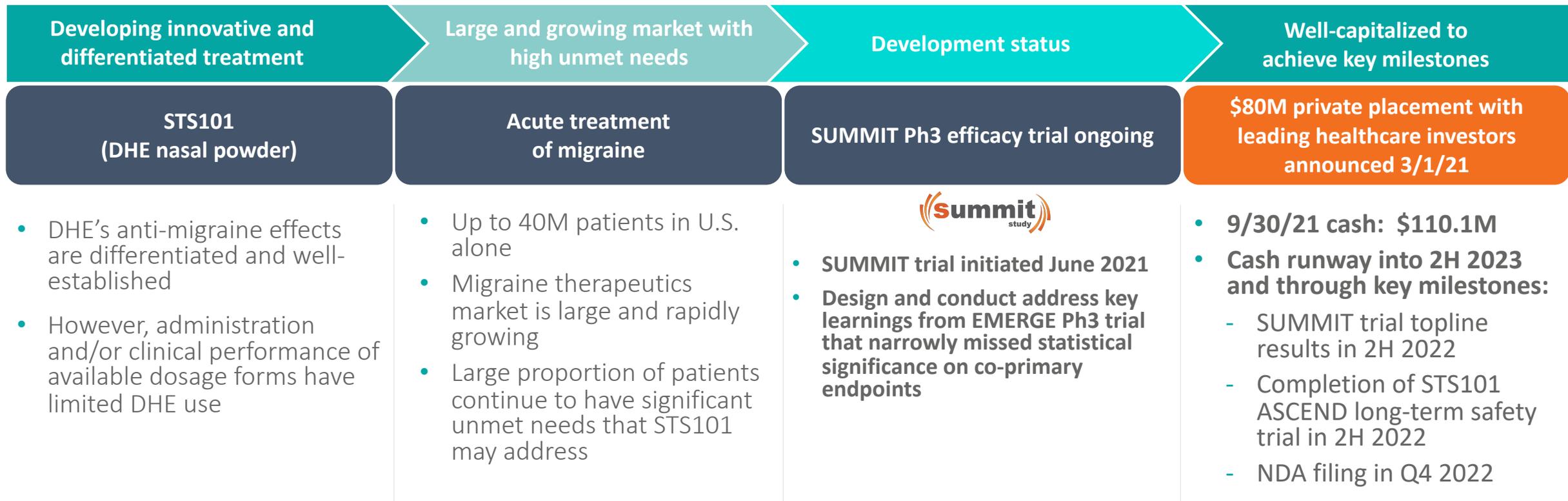
Know-how and trade secrets related to the STS101 formulation, delivery device, and manufacturing processes

- Historically, drug-device combinations are challenging to genericize (e.g., ADVAIR®)
- STS101 is the result of extensive formulation and device R&D over a long period of time

- Cash, cash equivalents and marketable securities as of 9/30/2021: \$110.1M
- \$80M private placement of common stock announced 3/1/2021
  - Financing led by Commodore Capital and New Enterprise Associates, with participation from existing shareholders and new investors
- Total shares outstanding as of 11/5/2021: 31.5M
- Cash, cash equivalents and marketable securities expected to fund operations into 2H 2023 and through key milestones

Financial results	Q3 2021	YTD 2021
R&D	\$10.2M	\$25.8M
G&A	3.2M	9.8M
Net loss	\$(13.3M)	\$(35.6M)
Accumulated deficit at 9/30/2021		\$(126.2M)

# Summary



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**Thank you**

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