# Strengthening our global leadership in treatment of addiction

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## Forward Looking Statements

*This presentation contains certain statements that are forward-looking and which should be considered, amongst other statutory provisions, in light of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty as they relate to events or circumstances that will or may occur in the future. Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding our financial guidance for 2015 and our medium- and long-term growth outlook, our operational goals, our product development pipeline and statements regarding ongoing litigation.*

*Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Suboxone Tablet, Suboxone Film, Subutex Tablet and any future products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of the Suboxone Film patent litigation relating to the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.*

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# Indivior PLC – who we are

## Global Leader in Treatment of Opioid Dependence

- 2015 Sales >$1bn
- Mainly Suboxone® brand

## Public Company since December 2014

- UK Domiciled
- London Listed

## US Based Business

- 80% of sales in US
- HQ in Richmond, Va.

## Experienced management team

- Built business from c.$35m (£21m) sales in 2003.

# Addiction – A Global Epidemic affecting many millions

- Our ambition is to strengthen our global leadership in addiction, growing via new product launches and geographic roll-out.
- We are global leaders in treatment of opioid dependence, which affects c.23m people globally
- 150m plus worldwide are dependent on opioids, cannabis, cocaine and other stimulants plus alcohol.
- We are expanding our portfolio into other dependencies (eg Alcohol) and to addiction-related co-morbidities (Schizophrenia).

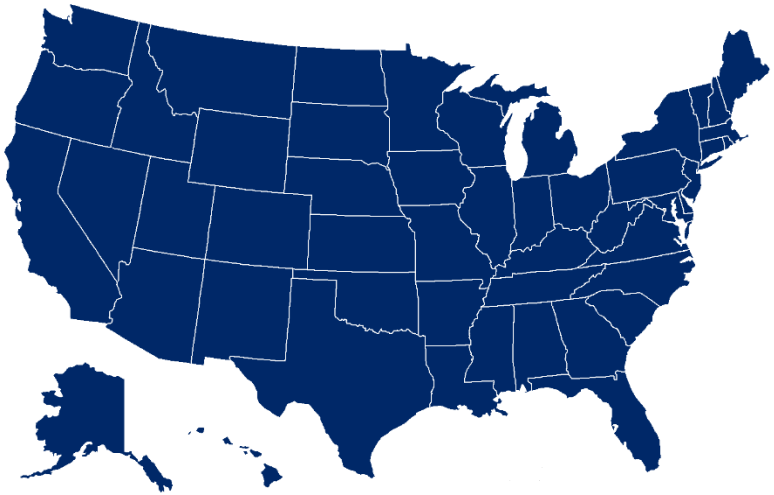
Indivior PLC annual report 2015 p.13. Full details of sources on p.137 but primarily UNODC World Drug Report 2015; UNODC Executive Director Statement June 26, 2015; WHO Global Status on Alcohol & Health 2014.


# OUR VISION

That all **patients** around the **world** will have **unrestricted access** to **high quality treatment services** for the chronic relapsing **conditions and co-morbidities of addiction**

# Opioid Dependence

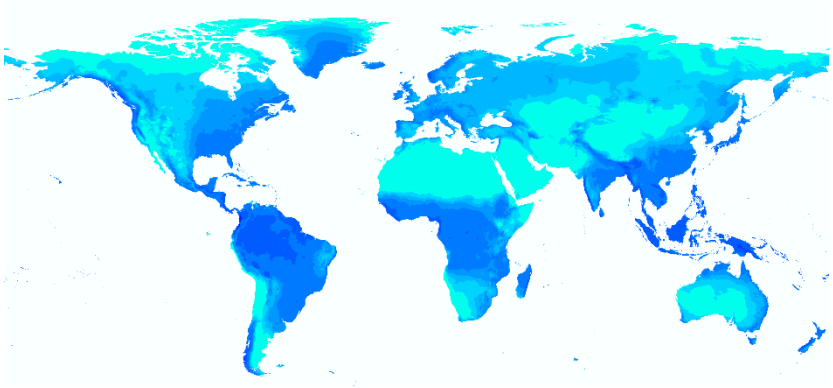
## Medication assisted treatment market is very US-based currently



- US accounts for substantial majority (80%+) of buprenorphine based medication assisted treatment for opioid dependency by value
- Around 2.5m potential patients, the majority of whom are addicted to prescription painkillers (rather than heroin).[1]
- Supportive government policy: treatment under the DATA 2000 act allowed in Doctor's surgery by certified physicians. Covered by health plans and Affordable Care Act.
- Net sales of buprenorphine based treatment in US estimated >$1bn pa[2]
- US will, therefore, remain the key determinant of Indivior's prospects in the short to medium term.

1. 2014 National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration (SAMSHA)
2. Based on $855m Indivior Revenues in USA in 2014, and share of 59%.

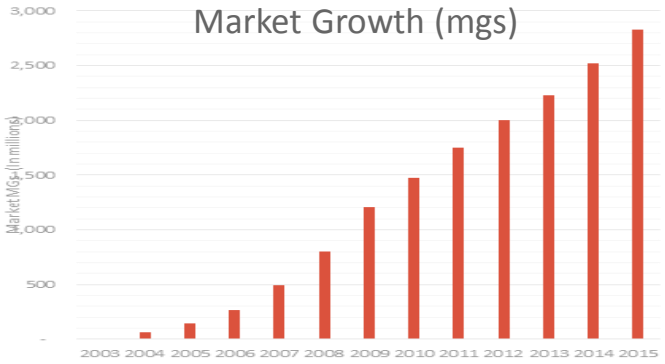
# Ex-US markets in earlier stage of development

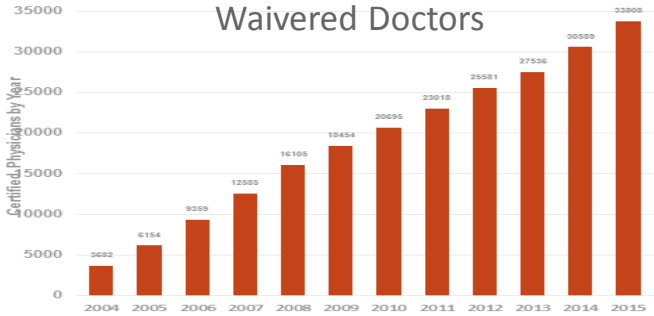


- **EU (>1m patients) differs from US as opioid-dependence mainly heroin addiction[1]**
  - Policy focused more on harm reduction for society than on patient recovery
  - Methadone clinics, strict supervision prevail
  - Volume growing slowly, value in decline due to austerity pressures
  - Scope to grow by building recognition of painkiller dependence (estimated up to 0.45m patients)
- **ROW (~20m patients) almost exclusive heroin addiction[1]**
  - Under-developed or adversarial policy regimes (penal sentences for possession)
  - China (c.7m opioid dependent; 1.4m registered drug users) the largest potential market – a strategic target for Indivior
  - Australia a well developed market on US model
- **Scope for growth in ex-US markets in the medium to long-term.**

1. 2015 World Drug Report. European Drug Report 2015 (EMCDDA): China Narcotics Control Report, 205-2014, NNCC Office.

# Growth continues in US



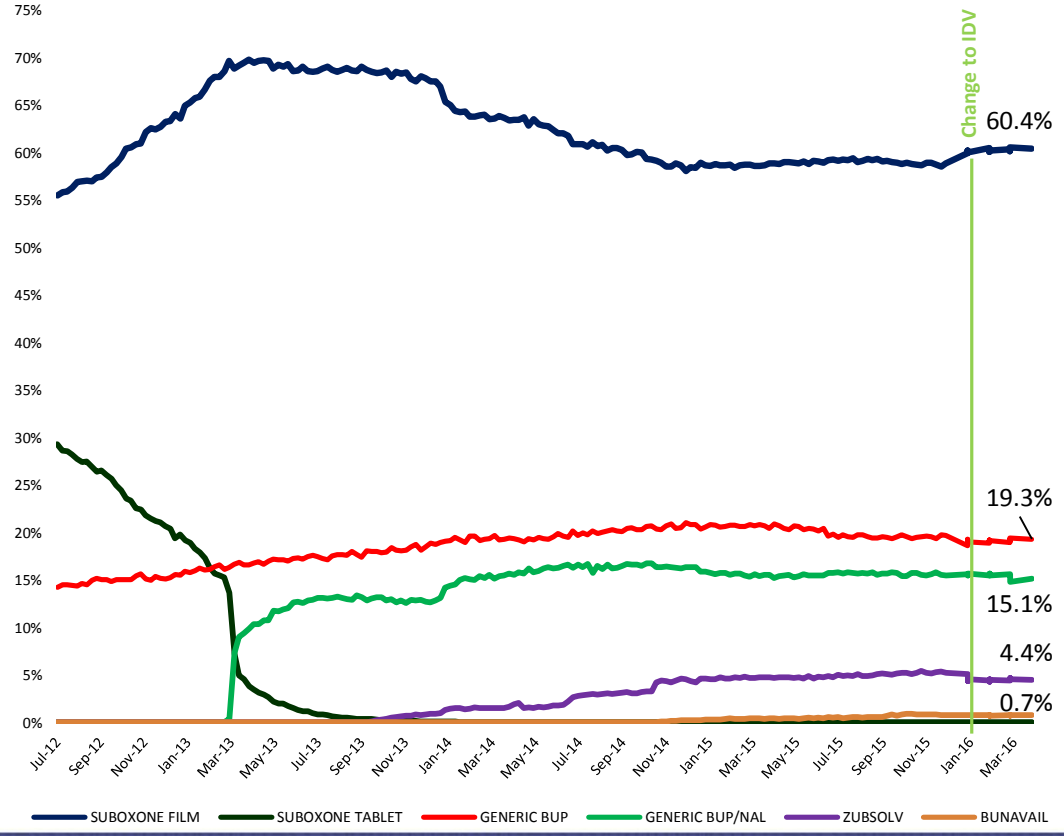




"The United States is experiencing an epidemic of drug overdose. During 2014, 47,055 drug overdose deaths occurred, 61% (28,647) involved some type of opioid, including heroin" (Source: CDC)

- Growing medically assisted treatment (MAT) based on buprenorphine led by
  - Rising use of prescription painkillers
  - Increasing certification (waivering) of doctors to provide MAT
  - Boosted in recent years by provision of treatment under Affordable Care Act
  - Growth in low double digits in 2014/15, slowing to high single digits in 2016 as ACA benefit annualised.
- Volume outlook remains positive, boosted by proposals from President Obama, HHS and Congress to expand access to treatment.
  - Raising 100 patient cap for waivered physicians; allowing nurse practitioners to prescribe

# Indivior market share stabilized

Source: IDV. Note database rebased from 1/1/2016




- Suboxone® film remains clear leader
- Competition from 5 generic and 3 branded bup/nal competitors but these have made limited impact
- Category pricing has been pressured by aggressive rebating/discounting by rivals in connection with formulary access
- But took modest price increase in January 2016
- US revenues grew 6% in Q1 2016

# Strong operational & financial delivery

- Successful defence of Suboxone® Film share in US against increasing competition
  - 2014: 62%, 2015: 59%; Q1 2016: 60%
- Gross margin maintained at 90%
- Financial guidance lifted twice in 2015
- Q1 2016 results ahead of plan
- 2016 guidance allows for significant $35m+ uplift in R&D and pre-commercialization investment
- Strong cash-flow has reduced net debt from $428m (FY2014) to $83m (Q1 2016)

| $m | 2015 Initial Guidance | 2015 Actual Results |
|---|---|---|
| Revenue | 850-880 | 1,014 |
| Net Income | 130-155 | 228 |

| $m | 2016 Guidance |
|---|---|
| Revenue | 945-975 |
| Net Income | 155-180 |

# Mixed Scorecard in R&D

| Product | Stage of Development | Estimated Approval * |
|---|---|---|
| **Buprenorphine Lifecycle** | | |
| Suboxone® Tablet China | Phase III Complete in China | 2018 |
| Suboxone® Film - China | CTA China approved Q4 2015 | tbc |
| RBP-6000 Buprenorphine Monthly Depot | Phase III<br>- Efficacy Q3 2016<br>- Safety H1 2017 | 2017 ** |
| **Alcohol Use Disorders** | | |
| Arbaclofen Placarbil | Phase IIA Study | 2020 |
| **Adjacency - Schizophrenia** | | |
| RBP-7000 Risperidone Monthly Depot | Phase III<br>- Efficacy Q2 2015<br>- Safety Q4 2016 | 2018 |

- R&D always carries risk, and 2015-16 has seen some setbacks in the pipeline
  - Nasal Naloxone :
  - RBP 6300 oral swallowable capsule of Buprenorphine Hemiadipate Phase 1
  - Suboxone® Film EU
- Crucially, the business-critical potential game changer – RBP 6000 monthly depot of buprenorphine, is on track in US (Phase III efficacy expected end Q3 2016)
  - Target US approval in 2017; target EU approval 2020.
  - Fast Track Designation Granted May 2016
- Other key projects progressing broadly on plan
  - RBP-7000 - Risperidone monthly depot for treatment of schizophrenia, target US approval mid 2018.
  - Arbaclofen Placarbil (alcohol use disorder), target US approval 2020, Phase IIa Q3 2016
  - Suboxone® Tablet in China, target approval 2018.

*best estimates only. ** assuming FDA grant priority review.

# More on key asset – RBP-6000

## Monthly Depot Buprenorphine

- Proven Atrigel® sub-cutaneous system
- Phase III on track – efficacy trial due to read out late Q3 2016
- Granted Fast Track Designation May 2016
- Target US approval late 2017
  (assuming FDA grant priority review.)
- EU clinical path to be determined late 2016

## Objectives of development

- Higher patient compliance
- Reduced diversion & misuse
- Target plasma levels of buprenorphine and μOR occupancy requirements that are effective for both withdrawal suppression **AND** opioid blockade.

**001 (Efficacy Study) Interim TLFs Q3 2016** → **NDA Submission Q2 2017** → **FDA Approval Q4 2017 (if FDA Priority Review granted)** → **Promotional Launch End 2017**

# ANDA litigation update

- 6 Generic companies seeking to commercialise generic versions of Suboxone® Film in US
- Indivior has asserted 3 orange-book listed patents (expiry 2023-2030) and 2 process patents in litigation with these filers
- **District court decision announced Friday June 3rd, 2016 found that Actavis & Par infringed the '514 patent which expires 2024.**
  - **'514 patent validity upheld and infringed**
  - **'150 patent validity upheld but not infringed.**
  - **'832 patent claims invalid but would have been infringed if valid.**

Timetable

| ANDA Applicant | Patents asserted against Filer | Trial Date | 30 Month Stay Expires |
|---|---|---|---|
| Actavis<br>Par | 3 Orange Book | Nov/Dec 2015 | 28 Feb 2016 (Actavis)<br>25 Sept 2016 (Par) |
| Teva | 3 Orange Book | Nov 2016 | 17 April 2017<br>(Teva has challenged the applicability of the 30-month stay as to one of its two ANDAs) |
| Actavis, Par, Teva | 2 Process | Nov 2016 | n/a |
| Alvogen | 3 Orange Book<br>2 Process | April 2017 | 29 Oct 2017 |
| Mylan<br>Sandoz | 3 Orange Book | Sept 2017 | 23 Mar 2018 (Mylan)<br>1 Apr 2018 (Sandoz) |

## ANDA Litigation Update

- Trial in the lawsuits against Actavis and Par involving the Orange Book-listed patents for Suboxone® Film November and December 2015, and post-trial briefing concluded in March 2016. Ruling announced June 3rd, 2016 finding infringement of '514 patent claims.
- Trial against Teva, Actavis and Par in the lawsuits involving the two recently granted process patents (US Patent No. 8,906,277 and US Patent No. 8,900,497) scheduled for November 2016.
- Trial against Teva in the lawsuit involving the Orange Book-listed patents for Suboxone® Film scheduled for November 2016, with Teva's 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17th, 2017. Indivior believes Teva's 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17th, 2017, however, Teva disputes the applicability of the stay to this ANDA.
- Trial against Alvogen in the lawsuit involving the Orange Book-listed patents and process patents for Suboxone® Film scheduled for April 2017, with Alvogen's 30-month stay of FDA approval expiring October 29th, 2017.
- Trial against Mylan and Sandoz in the lawsuit involving the Orange Book-listed patents for Suboxone® Film is scheduled for September 25th, 2017, with Mylan's stay expiring March 23, 2018 and Sandoz's stay expiring April 1, 2018.
- Indivior received a Paragraph IV notification from Teva, dated February 8, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of Buprenorphine/naloxone sublingual film. Indivior filed suit on March 21, 2016 which triggered a 30-month stay of approval of Teva's 505(b)(2) NDA. The parties have agreed that the outcome of this case will be dictated by the result of the November trial against Teva, with the infringement of the 16mg/4mg product governed by the result Indivior obtains for the 8 mg/2 mg ANDA strength in the November trial.

# Other Legal Proceedings

## DoJ Investigation

A federal criminal grand jury investigation of Indivior initiated in December 2013 is continuing, and includes marketing and promotion practices, pediatric safety claims, and overprescribing of medication by certain physicians. The United States Attorney for the Western District of Virginia has served a number of subpoenas relating to Suboxone® Film, Suboxone® Tablet, Subutex® Tablet, Buprenorphine and the Group's competitors, among other issues. Indivior is in the process of responding by producing documents and other information in connection with this ongoing investigation. It is not possible at this time to predict with any certainty or to quantify the potential impact of this investigation on the Company. Indivior is cooperating fully with the relevant agencies and prosecutors and will continue to do so.

## FTC & Class Action

- Fact discovery is underway in the antitrust class actions.
- Amneal LLC, a manufacturer of generic buprenorphine / naloxone tablets, has joined the litigation as an additional plaintiff.
- FTC /State AG investigation continues to focus on privilege document dispute and litigation

# External routes to Growth

## Expand Global Treatment Access

### Expand treatment in USA = Grow the Market

- More physicians trained and waivered
- Increased awareness of treatment
- Reduced barriers to treatment access

### Opioid painkiller dependence in Europe

- 475K plus patient population unrecognised
- Growing awareness of condition

### Clinical trials for Suboxone® in China

## Inorganic Growth Strategy

### Business Development in Addiction

- Deep understanding of science of addiction and knowledge of landscape of opportunities
- Will bring assets in house at opportune time

### Adjacencies where our model works

- Focus on disease space where we add value
  - Intensive market development
  - Behavioural modification focus
  - Sticking to our knitting

### Transformative M&A not on radar

# Indivior PLC – Priorities for 2016

**The ANDA ruling has secured greater medium-term certainty for Company**

## 1.Suboxone® Film Resilience

Preserve leadership position in USA against 5 generic and 3 branded competitors

## 2. Develop the pipeline

- Transformational lifecycle product for Buprenorphine
- Treatments for other addictions and addiction rescue

## 3. Refinance Company ready for BD / M&A

- Expand business
- diversify business risk

through targeted business development

## 4. Expand Global treatment

- New treatment areas of addiction and related morbidities
- Expand treatment access in USA
- Opioid painkiller dependence in Europe

# Summary


We face the future with renewed confidence
Our confidence in the strength of our IP has been confirmed
We look forward to sharing our progress in 2016

**Indication**

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII) is a prescription medicine indicated for treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

**Treatment should be initiated under the direction of physicians qualified under the Drug Addiction Treatment Act.**

**Important Safety Information**

Do not take SUBOXONE® Film if you are allergic to buprenorphine or naloxone as serious negative effects, including anaphylactic shock, have been reported.

SUBOXONE® Film can be abused in a manner similar to other opioids, legal or illicit.

SUBOXONE® Film contains buprenorphine, an opioid that can cause physical dependence with chronic use. Physical dependence is not the same as addiction. Your doctor can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE® Film suddenly without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

SUBOXONE® Film can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other medications that act on the nervous system (ie, sedatives, tranquilizers, or alcohol). It is extremely dangerous to take nonprescribed benzodiazepines or other medications that act on the nervous system while taking SUBOXONE® Film.

You should not drink alcohol while taking SUBOXONE Film, as this can lead to loss of consciousness or even death.

Death has been reported in those who are not opioid dependent. Your doctor may monitor liver function before and during treatment.

SUBOXONE® Film is not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. However, SUBOXONE® Film may be used with caution for maintenance treatment in patients with moderate hepatic impairment who have initiated treatment on a buprenorphine product without naloxone.

Keep SUBOXONE® Film out of the sight and reach of children. Accidental or deliberate ingestion of SUBOXONE Film by a child can cause severe breathing problems and death.

Do not take SUBOXONE® Film before the effects of other opioids (eg, heroin, hydrocodone, methadone, morphine, oxycodone) have subsided as you may experience withdrawal symptoms.

Injecting SUBOXONE® may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

Before taking SUBOXONE® Film, tell your doctor if you are pregnant or plan to become pregnant. If you are pregnant or become pregnant while taking SUBOXONE Film, alert your doctor immediately and you should report it using the contact information provided below.*

Neonatal withdrawal has been reported following the use of buprenorphine by the mother during pregnancy.

Before taking SUBOXONE® Film, talk to your doctor if you are breastfeeding or plan to breastfeed your baby. SUBOXONE® can pass into your breast milk. You and your doctor should consider the development and health benefits of breastfeeding along with your clinical need for SUBOXONE® Film and should also consider any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBOXONE® Film affects you. Buprenorphine in SUBOXONE® Film can cause drowsiness and slow reaction times during dose-adjustment periods.

Common side effects of SUBOXONE® Film include nausea, vomiting, drug withdrawal syndrome, headache, sweating, numb mouth, constipation, painful tongue, redness of the mouth, intoxication (feeling lightheaded or drunk), disturbance in attention, irregular heartbeat, decrease in sleep, blurred vision, back pain, fainting, dizziness, and sleepiness.

This is not a complete list of potential adverse events associated with SUBOXONE® Film. Please see full Prescribing Information for a complete list.

*To report negative side effects associated with taking SUBOXONE® Film, please call 1-877-782-6966. You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about SUBOXONE Film, SUBOXONE® (buprenorphine and naloxone) Sublingual Tablets (CIII), or SUBUTEX® (buprenorphine) Sublingual Tablets (CIII), please see the respective full Prescribing Information and Medication Guide at www.IndiviorREMS.com.

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