+91& 8SFUXMTY

*INY   Q <J(IF\ /ZQ^

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YMJ HTQQJHYN[J N NLM
TSJ TK TZW WJHJSY UFSJ
INXHZXXNTSX \MJW   QJF
FHWTXX XYWFYJL^   HNJ
HTRRJWHNFQN_FYN S HF
YTLJYMJW YT ZSUF \ \MI
WJFQQ^ YFPJX YT G ZSH
*WXY YNRJ <J MTU YMN
XJW[JX FX F LZNIJ   I F
XTZWHJ TK HTS*IJS J FX
UW\UFW^\JKTW \^MN XY
JXXJSYNFQ \TWPX YWJFR

4WHMJXYW 9NRJ 1FZSHM 8ZH <TWPXYWJFR 5

9MNX NSFZLZWFQ JINYNTS TK YMJ +91& 8SFUXMTY XZRRFWN JX PJ^ NSXNLYX
WJHJSY UFSJQ INXHZXXNTS \MNHM J]UQTWJI YMJ KTZW JXXJSYNFQ \TWPXYWJFR
9NRJ 1FZSHM

4ZW UFSJQ TK NSIZXYW^ QJFIJWX \NYM IJJU *WXY YNRJ QFZSHM N]UJWNJSHJ
YT XUTYQNLMY YMJ WJFQ \TWQI HTRUQJ]NY^ HWTXX KZSHYNTSFQ NSYJLWFYNTS
\NXITR YMFY IJ*SJ XZHHJXXKZQ QFZSHMJX NS YMJ JRJWLNSL (QNSNHFQ (TRRJWHNFQ
<MJYMJW ^TZ FWJ NS 8YWFYJLNH (QNSNHFQ (TRRJWHNFQ TW 4UJWFYNTSX WTT
HTRRZSNHFYNTS FRTSL INKKJWJSY LWTZUX NX HWNYNHFQ YT WJIZHJ XNQT NFSI
FQNLSJI YT\FWIX F XZHHJXXKZQ *WXY YNRJ QFZSHM

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2NHMJQJ   2FWY^ -ZLMJ   &^NXMF
(*4   *]JHZYN[J)NWJ   (TRRJWHNFQ *]JHZYN[J
&ZXYWFQNX 5MF\   .RRZSJJWNSL

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<NYM TUJS HFSINI INFQTLZJ FHWTXX KZSHYNTSX YNRJQN
I^SFRNHX FY UQF^ MJWJcX XTRJ YMJRJ YFPJF\F^X KWTR
^TZW OTZWSJ^

🔁 4[JWQFUUNSL 7TQJX &HHJQJWFYJI 9NRJQNSJX

&^JXMF WJXTSFYJI \NYM TZW TSJ UFLJW +NWXY 9NRJ 1FZSHM &Q
WJHTLSN_NSL YMFY RTXY ITScY PST\ \MFYcX MFUUJSNSL FY YMJ X
FSI TKYJS HTRRZSNHFYNTS HFSSTY GJ T[JWXTQI

2FWY^ WJ+JHYJI HFSINIQ^ TS YMJ +91 WJFQNY^ NS XRFQQ HTRUF
\TWPXYWJFRX GQZW 9JFRX \JFW RZQYNUQJ MFYX WJVZNWNSL FQN
HTRRZSNHFYNTS

> *"In large pharma, functions are distinct. In FTLs, it's often the same people across workstreams, which makes alignment even more critical."* – Marty

✳️ (TWUTWFYJ 8YWFYJL^ 'JLNS <NYM YMJ *SI NS 2NS

> *"Launch readiness starts at pre-IND   Engage with FDA early, they are a very important partner in launch readiness"* - Michele

2NHMJQJ JRUMFXN_JI IJ*SNSL XZHHJXX JFWQ^ <MFY ITJX QFZSHM
RJFXZWJ NY$)J(JQTUNSL F XYWTSL 9FWLJY 5WTIZHY 5WT*QJ 955
XYFW YT FQNLS NSYJWSFQ YJFRX NS[JXYTW XYWFYJL^ FSI J]YJW

8HJSFWNT UQFSSNSL FSI UWTFHYN[J WNXP RNYNLFYNTS FWJ FQX
YT XYF^ FLNQJ NS YMJ KFHJ TK NSJ[NYFGQJ ZSHJWYFNSY^)JQF^
WJFINSJXX HFS ZSWF[JQ FQNLSRJSY \NYM HTWUTWFYJ LTFQX

> *"Scenario planning isn't optional—it's essential. Have the tough conversations early, not reactively."* –Ayesha
> *"There's never enough cash-on-hand, raising money proactively is critical, be ready for delays.."* –Michele

🔬)WZL)J[JQTURJSY 5MFXJ &UUWTUWNFYJ)JHNXNT

+91X RZXY GJ RNSIKZQ TK UFXJ FUUWTUWNFYJ IJ[JQTURJSY 2F
IFYF NS 5MFXJ . J L fUZY YMJ &5. NS F HFUXZQJ KFXYg \MNQJ
XZUUQNJW WJQFYNTSXMNUX ST\ FSI YMWZ QFYJW UMFXJX 5MFXJ
WJIZSIFSH^ FSI ()24 UFWYSJWXMNUX YMFY HFS \NYMXYFSI YFWN

9MNSP FGTZY WNXPX FSI XZUUQ^ HMFNS WJIZSIFSH^ ^ ZSIJWXYFS
XTQNI MNXYTW^ TK ,25 HTRUQNFSHJ FSI HTS*IJSHJ NS XZUUQ^ HT

&QXT JRUMFXN_JI ITScY \FNY YT GWNSL NS 7JLZQFYTW^ *FWQ^
IJXNSFYNTSX QNPJ TWUMFS TW WFWJ UJINFYWNH \MNHM FWJ N

> *"Don't overbuild early, but don't wait to engage key partners like FDA and CDMOs either. Launch excellence requires sequencing and foresight."* – Marty

.S WJXUTSXJ YT F QN[J VZJXYNTS WJLFWINSL TZW J]UJWNJSHJX F

> *"Having the right clinical end points in the trial are critical to help you build a stronger value story"*

💼 (TRRJWHNFQN_FYNTS 2FWPJY &HHJXX 2ZXY 8YFW

&^JXMF JRUMFXN_JI YMFY RFWPJY FHHJXX UQFSSNSL XYFWYX ^JW
XYWFYJL^ XYFPJMTQIJW JSLFLJRJSY FSI 51 FSI INXYWNGZYNTS
SJLTYNFYNTSX \NYM XUJHNFQY^ INXYWNGZYTWX YMJ 'NL   FSI U
YT QTSL YJWR XZXYFNSFGNQNY^

.RUTWYFSYQ^ RFSZKFHYZWJWX HFS XUJFP YT UF^TWX UWJ FUUW
9MJXJ JFWQ^ INFQTLZJX XMTZQI NSYWTIZHJ YMJ HTRUFS^ GWFSI
YMJ FXXJY

> *"Pricing is not just research—it's reputation. Get it right the first time."* – Ayesha

🏢 *SYJWUWNXJ *SFGQJRJSY -NWNSL (ZQYZWJ 2FY

2ZQYNUQJ UFSJQNXYX \FWSJI TK RNXRFYHMJI MNWNSL YNRNSL_Y
JJJHYZTS 9JFRX XMTZQI FQNLS MNWNNSL, candidate domination, to miljs
mid- and late-clinical testing, NDA acceptance, T-6 PDUFA).

2NHMJQJ XMFWJI YMFY JIZHFYNTS NX F INKKJWJSYNFYTW_STY OZ
FQXT NSYJWSFQQ^ *[JW^TSJ KWTR HTRRJWHFQ YT VZFQNY^ XMT
RJHMFSNXR TK FHYNTS FSI \M^ YMJ YMJWFU^ RFYYJWX

> *"Hire the right team for this launch, not just any launch. You need the right experience, mindset, and passion to appropriately support the patients in this disease area."* – Michele

01 0JJU YMJ UFYNJSY FY YMJ HJSYJW TK J[JW^YMNSL ^TZ IT &XP ...T\ \N...

02 8JJP FSI PJJU YMJ JSI NS RNSI GJKTWJ XYFWYNSL J]JHZYNTS_F... FS^...

03 -NWJ YMJ WNLMY UJTUQJ FY YMJ WNLMY YNRJ FSI HWJFYJ FS J... IWTS...
WNLMY VZJXYNTSX FSI RFPNSL NY XFKJ KTW ^TZ YJFR YT GWNS ...ZU Y...
XTQZYNTSNSL

04 (TRRZSNHFYJ JFWQ^ FSI TKYJS_FY FQQ QJ[JQX)TScY FXXZRJ J...JW^TS...
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05 >TZ HFS GWJFP IT\S YMJ XNQTJX GZY XJJP YT GZNQI GWNILJX   HFX...
\NQQ WJRFNS 5WTFHYN[JQ^ WJFHM TZY NS[NYJ UJTUQJ FSI J] WYN...

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HTQQFGTWFYNTS FSI HTS*IJSHJ

9MJ QJXXTS HFUYZWJI MJWJ FWJ XMFUJI G^ Y... JJ...
KZSHYNTSFQ QJFIJW \TWPNSL YMWTZLM YMJ H...RUQ...
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^TZW YJFR YTLJYMJW FX ^TZ RT[J KWTR XHNJ... U YT...

9MNX KWFRJ\TWP TK KTZW JXXJSYNFQ \TWPXY... FRX...
\JGNSFWX MTXYJI G^ YMJ +91& *FHM XJXXNT... QQ ...
HMFQQJSLJX FSI GJXY UWFHYNHJX \NYMNS FSI ...WTZ...
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Coming Soon!

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YNRJ QFZSHM TW XZGXJVZJSY QFZSHMJX TK HTRRJWHNFQ GNTU...
\NYM XYWFYJLNH INWJHYNTS UWT[NIJI G^ YMJ J]JHZYN[J HTRRNYY...
HTRRZSNY^ YMFY XMFWJX PST\QJILJ IWN[JX NSST[FYNTS FSI JQJ[...
ZU KTW XZHHJXX FSI J[JW^ UFYNJSY GJSJ...

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