

!" #&/

4;O <548G=>3> 70AB>AC20==O ;V:0@AL:>3> 70A>1C

(ALERZIN®)

!;:04:

4VNG0 @5G>28=0: ;52>F5B8@878=C 483V4@>E;>@84;

1 B01;5B:0

4>?>28=8: F5;N;>70 :@5<=VT20 :@8AB0;VG=0, 3V4@>:A8?@>?V;F5;N;>70 =87L:>7078 <=>3V4@0B,
<03=VN AB50@0B;

A:;04 >1>;>=:8: Opadry II 33G28523 1V;89 (3V?@<5;>70, B8B0=C 4V>:A84 (171), <0:@>3>; 3350,
B@80F5B8;3;VF5@8=, ;0:B>78 <=>3V4@0B).

V:0@AL:0 D>@<0. "01;5B:8, 2:@8BV ?;V2:>2>N >1>;>=:>N.

A=>2=V DV78:>-EVABV: 1V;>3> 01> <0965 1V;>3> :>;L>@C :@C3;V, ?>42>>?C:;V B01;5B:8, 2:@8BV
?;V2:>2>N >1>;>=:>N, 157 70?0EC 01> <0965 157 70?0EC, 7 3@02V@C20==O< AB8;V7>20=>W ;VB5@8
<E» 7 >4=>3> 1>:C B0 =><5@>< «281» 7 V=H>3>.

\$0@<0:>B5@0?52B8G=0 3@C?0. □=B83VAB018 4;O A8AB5<=>3> 70AB>AC20==O. >EV4=V
?V?5@078=C. >4 "" R06A 09.

\$0@<0:>;>3VG=V 2;0AB82>ABV.

\$0@<0:>48=0

52>F5B8@878= F5 0:B82=89 AB01V;L=89 R-5=0=BV<5@ F5B8@878=C, I> =0;568BL 4> 3@C?8
:>=:C@5=B=8E 0=B03>=VABV2 3VAB0

1-3VAB028E @5F5?B>@V2. !?>@V4=5=VABL 4>1-3VAB028E @5F5?B>@V2 C ;52>F5B8@878=C C 2
@078 28I0, =V6 C F5B8@878=C. ?;820T =0 3VAB0728B:C 0;5@3VG=>W @50:FVW, 7<5=HCT
78=>DV;V2, AC48==C ?@>=8:=VABL, >K56CT 282V;L=5==O <54V0B>@V2 70?0;5==O. >?5@5460T
@>728B>: B0 ?>;53HCT ?5@51V3 0;5@3VG=8E @50:FV9, G8=8BL 0=B85:AC40B82=C,
?@>B8A25@1V6=C, ?@>B870?0;L=C 4VN, <0965 =5 G8=8BL 0=B8E>;V=5@3VG=>W B0
0=B8A5@>B>=V=>2>W 4VW.

\$0@<0:>:V=5B8:0.

\$0@<0:>:V=5B8G=V ?0@0<5B@8 ;52>F5B8@878=C <0NBL ;V=V9=C 70;56=VABLV <0965 =5
2V4@V7=ONBLAO 2V4 B0:8E C F5B8@878=C.

IA>@1FVO. @5?0@0B ?VA;O ?5@>@0;L=>3> 22545==O H284:> B0 V=B5=A82=> ?>3;8=0TBLAO.

!BC?V=L 2A<:BC20==O ?@5?0@0BC =5 70;568BL 2V4 4>78 ?@5?0@0BC B0 =5 7<< W6V, 0;5<0:A8
<0;L=0 :>=F5=B@0FVO (!_{m0E}) ?@5?0@0BC 7<5=HCTBLAO B0 4>AO30T A2>3> <0:A8<0;L=>3>
7=0G5==O ?V7=VH5. V>4>ABC?=VABL 4>AO30T 100 %.

50 % E2>@8E 4VO ?@5?0@0BC @>72820TBLAO G5@57 12 E2 ?VA;O ?@89>4=>@07>2>W 4>78, 0 C
95 % G5@57 0,5-1 3>48=C. !_{m0E} C A8@>20BFV :@>2V 4>AO30TBLAO G5@57 50 E2 ?VA;O
>4=>@07>2>3> ?@89> B5@0?52B8G=>W 4>78 B0 CB@8BO3>< 2 4=V2. !_{m0E} AB0=>28BL 270 =3/<;
?VA;O >4=>@07>2>3> 70AB>AC20==O V 308 =3/<; ?VA;O ?>2B>@=>3> 70AB>AC20==O C 4>7V 5 <3
2V4?>2V4=>.

>7?>4V;. V4ACB=O V=D>@<0FVO I>4> @>7?>4V;C ?@5?0@0BC C B:0=8=0E ;N48=8, 0 B0:>6 I>4>
?@>=8:=5==O ;52>F5B8@878=C :@V7L 35<0B>5=F5D0;VG=89 10@T@. # 4>A;V465==OE =091V;LH0
:>=F5=B@0FVO 70DV:A>20=0 C ?5GV=FV B0 =8@:0E, 0 =09=86G0 C B:0=8=0E F5=B@0;L=>W
=5@2>2>W A8AB5<8. 1T< @>7?>4V;C 0,4 ;/:. 2O7C20==O 7 1V;:0<8 ?;07<8 :@>2V 90 %.

V>B@0=AD>@<0FVO. >@30=V7 14 % ;52>F5B8@878=C. @>F5A <5B01>;V7:A840FVN, N- B0 -
450;:V;C20==O V A?>;CG5==O 7 B0C@8=>C20TBLAO 7 CG0ABN F8B>E@>4V O: C ?@>F5AV
>:A840FVW 15@CBL CG0ABL G8A;5==V B0 (01>) =5287=0G5=V V7>D>@<8 CYP. 52>F5B8@878= =5
2?;820T =0 0:B82=VABL F8B>E@<=8E V7>D5@<5=BV2 12, 2!9, 2!19, 2D6, 21, 34 C :>=F5=B@0FVOE,
I> 7=0G=> ?5@528ICNBL <0:A8<0;L=V ?VA;O ?@89=OBBO 4>78 5<3 ?5@>@0;L=>. @0E>2CNG8
=87L:89 ABC?V=L <5B01>;V7ABV 4> ?@83=VG5==O <5B01>;V7

82545==O. :A:@5FVO ?@5?0@0BC 2V41C20TB LAO 2 >A=>2=>: ;C1>G:>2>W DV;LB@0FVW B0
0:B82=>W :0=0;LF52>W A5:@5FVW. 5@V>4 =0?V2282545==O ?@5?0@0BC 7 ?;07<8 :@>2V C
4>@>A;8E ("1/2) AB0=>28BL 7,9 ± 1,9 3>48=8. 5@V>4 =0?V2282545==O ?@5?0@0BC :>@>BH89 C
<0;5=L:8E 4VB59. 030;L=89 ;V@5=A C 4>@>A;8E 0,63 <;E2/:3. >A=>2=>F5B8@878=C B0 9>3>
<5B01>;VBV2 7 >@30=V748BLAO 2 A5@54=L>W 4>78 ?@5?0@0BC). D5:0;VO<8 282>48BLAO ;8H5
12,9 % 70AB>A>20=>W 4>78 ?@5?0@0BC.
G5284=89 ;V@5=A ;52>F5B8@878=C 4;O >@30=V7@5;NT 7 ;V@5=A< :@50B8=V=C. "><0<8
;52>F5B8@878=C 7 C@0EC20==O< ;V@5=AC :@50B8=V=C. @8 0=C@VW ?@8 :V=F52V9 B5@
@N20==O =8@>: 7030;L=89 ;V@5=A >@30=V7@V2=O=> V7 7030;L=8< ;V@5=A< >@30=V7AV1 157
B0:8E ?>@CH5=L, 7<5=HCTBLAO ?@81;87=> =0 80 %. V;L:VABL ;52>F5B8@878=C, I> 282>48BLAO
?V4 G0A AB0=40@B=>W 4-3>48==>W ?@>F54C@8 35<>4V0;V7C, AB0=>28;0 < 10 %.

;V=VG=V E0@0:B5@8AB8:8.

>:070==O.

!8<0B8G=5 ;V:C20==O 0;5@3VG=>3> @8=VBC (C B>@VG=>3> 0;5@3VG=>3> @8=VBC) B0
:@>?82'O=:8.

@>B8?>:070==O.

V428I5=0 GCB;82VABL 4> ;52>F5B8@878=C 01> 4> 1C4L-O:>W V=H>W A;;04>2>W 40=>W
;V:0@AL:>W D>@<8, 01> 4> 1C4L-O:8E ?>EV4=8E ?V?5@078=C.
"O6:0 D>@<0 E@>=VG=>W =8@:>2>W =54>AB0B=>ABV (;V@5=A :@50B8=V=C <10<;E2).
V4:VA=V A?04:>2V 70E2>@N20==O =5?5@5=>A8>ABV 30;0:B>78, ;0:B07=0 =54>AB0B=VABL 01>
?>@CH5==O 70A2>T==O 3;N:>78 V 30;0:B>78.

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.

4=>G0A=5 70AB>AC20==O 7 0=B8?V@8=><, ?A524>5D54@8=><, F8<5B848=><, :5B>:=>07>;<,
5@8B@><, 078B@><, 3;V?V784>< 01> 4V075?0<>< =5 G8=8BL ;V=VG=> 7=0GCI8E =5A?@8OB;828E
270T<>4V9. !CAC20==O 7 B5>DV;V=>< (400 <3/4>1C) 7=86CT =0
16 % 7030;L=89 ;V@5=A ;52>F5B8@878=C (:V=5B8:0 B5>DV;V=C =5 7@8 4>A;V465==V
1030B>@07>2>3> 22545==O @8B>=02V@C (600 <3 2 @078 =0 4>1C) B0 F5B8@878=C (10 <3 =0 4>1C)
ABC?V=L 5:A?>78FVW F5B8@878=C 71V;LHC202AO ?@81;87=> =0 40 %, B>4V O: @>7?>4V;
@8B>=02V@C 45I> 7 ?0@0;5;L=>3> 22545==O F5B8@878=C.
5<0T 40=8E I>4> ?>A8;5==O 5D5:BC A540B82=8E 70A>1V2 ?@8 70AB>AC20==V C B5@0?52B8G=8E
4>70E. ;5 A;V4 C=8:0B8 70AB>AC20==O A540B82=8E 70A>1V2 ?V4 G0A ?@89>
52>F5B8@878= =5 ?>A8;NT 5D5:B 0;:>3>;N, >4=0: C GCB;828E ?0FVT=BV2 >4=>G0A=5
70AB>AC20==O ;5@78=C V 0;:>3>;N 01> V=H8E ?@5?0@0BV2, I> ?@83=VGCNBL DC=:FVN
F5=B@0;L=>W =5@2>2>W A8AB5<8, <>65 2?;820B8 =0 DC=:FVN F5=B@0;L=>W =5@2>2>W A8AB5
<8.
@89>< W6V =5 2?;820T=0 ABC?V=L 2A<:BC20==O ?@5?0@0BC, 0;5 >4=>G0A=5 26820==O W6V
7=86CT H284:VABL 9>3> 01A>@1FVW.

A>1;82>ABV 70AB>AC20==O.

>15@56=VABN 70AB>A>2C20B8 ?0FVT=B0< V7 E@>=VG=>N =8@:>2>N =54>AB0B=VABN
(=5>1EV4=0 :>@5:FVO @5687C20==O) B0 ?0FVT=B0< ;VB=L>3> 2V:C V7 =8@:>2>N =54>AB0B=VABN
(<>6;825 7=865==O ;C1>G:>2>W DV;LB@0FVW). V4 G0A 70AB>AC20==O ?@5?0@0BC A;V4 CB@8
3>;N.
@8 =0O2=>ABV C ?0FVT=BV2 ?52=8E D0:B>@V2, I> ?@>2>:CNBL 70B@82>W 70;>78) =5>1EV4=>
?@84V;8B8 C203C ?@8 287=0G5==V 4>78 ?@5?0@0BC, >A:V;L:8 ;52>F5B8@878=<>65 71V;LH8B8
@878: 70B@8

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

52>F5B8@878= ?@>B8?>:070=89 4;O 70AB>AC20==O C ?5@V>4 203VB=>ABV. 52>F5B8@878=
?@>=8:0T C 3@C4=5 <>;>:, B>1EV4=>ABV 70AB>A>2C20==O ?@5?0@0BC 3>4C20==O 3@C44N A;V4
?@8?8=8B8.

40B=VABL 2?;820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> V=H8<8
<5E0=V7<0<8.
!;V4 CB@8:5@C20==O 02B>B@0=A?>@B< 01> @>1>B8 7 V=H8<8 <5E0=V7<0<8 ?V4 G0A ;V:C20==O
?@5?0@0B>

!>AV1 70AB>AC20==O B0 4>78.
@5?0@0B ?@87=0G0B8 4>@>A;8< B0 4VBO< 2V:< 2V4 6 @>:V2 2=CB@VH=L> C 4>1>2V9 4>7V 5 <3
1 @07 =0 4>1C.
@89<0B8 B01;5B:C =570;56=> 2V4 26820==O W6V. "01;5B:C =5>1EV4=> :>2B0B8 FV;>N, 70?820NG8
=525;8:>N :V;L:VABN 2>48.
%2>@8< ;VB=L>3> 2V:C 7 =>@<0;L=>N DC=:FVTN =8@>: :>@5:FVO 4>78 ?@5?0@0BC =5 ?>B@V1=0.
%2>@8< V7 ?>@CH5=>N DC=:FVTN =8@>: @>7@0EC=>: 4>78 =5>1EV4=> ?@>2>48B8 7
C@0EC20==O< ;V@5=AC :@50B8=V=C 2V4?>2V4=> 4> B01;8FV.
;O 70AB>AC20==O FVTW B01;8FV 4>7C20==O =5>1EV4=> >FV=8B8 ;V@5=A :@50B8=V=C (:@)
?0FVT=B0 C <;E2. :@ (<;E2) <0T 1CB8 >FV=5=89 70 2< :@50B8=V=C C A8@>20BFV :@>2V (<3/4;) 70
4>?><3>N =0ABC?=>W D>@

:@ =
$$\frac{[140\ 2V: (@>:8)]\ x<0A0\ BV;0\ (:3)}{72\ x\ :@50B8=V= A8@>20B:8\ :@>2V\ (<3\ /4;)}\ (x\ 0,85\ 4;O\ 6V=>:)$$

>@5:FVO 4>78 ?@5?0@0BC 4;O E2>@8E V7 ?>@CH5=>N DC=:FVTN =8@>::

\$C=:FVO =8@>:	;V@5=A :@50B8=V=C, <;/ E2	>70 B0 :V;L:VABL ?@89>
>@<0;L=0 DC=:FVO =8@>:	≥ 80	5 <3 1 @07 =0 4>1C
>@CH5==O ;53:>3> ABC?5=O	50-79	5 <3 1 @07 =0 4>1C
>@CH5==O ?>3> ABC?5=O	30-49	5 <3 1 @07 =0 2 4>18
>@CH5==O BO6:>3> ABC?5=O	< 30	5 <3 1 @07 =0 3 4>18
V=F520 AB04VO 70E2>@N20==O =8@>.. 0FVT=B8, O:V ?5@51C20NBL =0 4V0;V7V	< 10	@>B8?>:070=>

VBO< V7 ?>@CH5==O<8 DC=:FVW =8@>: 4>7C ?@5?0@0BC A;V4 :>@83C20B8 V=482V4C0;L=> 7
C@0EC20==O< =8@>:2>3> ;V@5=AC B0 <0A8 BV;0.
%2>@8< 28=OB:>2> V7 ?5GV=:>2>N =54>AB0B=VABN :>@5:FVO @5687C20==O =5 ?>B@V1=0.
%2>@8< V7 ?5GV=:>2>N B0 =8@>:2>N =54>AB0B=VABN :>@83C20B8 @568< 4>7C20==O
2V4?>2V4=> 4> =02545=>W 28I5 B01;8FV.
"@820;VABL 70AB>AC20==O: ?0FVT=BV2 V7 ?5@V>48G=8< 0;5@3VG=8< @8=VB< (B@820;VABL A8
@N20==O AB0=>28BL < 4 4V1 =0 B8645=L 01> ?@>BO3< <5=H5 4 B86=V2) A;V4 ;V:C20B8
2V4?>2V4=> 4> 70E2>@N20==O B0 0=0<=57C; ;V:C20==O <>6=0 ?@8?8=8B8, O:I> A8<8 7=8=:CBL, B0
<>6=0 2V4=>28B8 7=>2C ?@8 ?>2B>@=>3> 0;5@3VG=>3> @8=VBC (B@820;VABL A8@N20==O
AB0=>28BL > 4 4V1 =0 B8645=L B0 ?@>BO3< 1V;LH5 4 B86=V2) C ?5@V>4 :>=B0:BC 7 0;5@35=0<8
?0FVT=BC <>65 1CB8 70?@>?>=>20=0 ?>ABV9=0 B5@0?VO. @8 E@>=VG=8E 70E2>@N20==OE
(E@>=VG=89 0;5@3VG=89 @8=VB, E@>=VG=0 :@>?82'O=:0) B@820;VABL ;V:C20==O AB0=>28BL 4>
1 @>:C.

VB8.
@5?0@0B C 283;O4V B01;5B>: =5 70AB>A>2C20B8 4VBO< 2V:< 2V4 6 @>:V2, >A:V;L:8 FO
;V:0@AL:0 D>@<0 =5 40T 7<>38 ?@>2>48B8 =5>1EV4=C :>@5:FVN @5687C20==O. 0=V9 :0B53>@VW
?0FVT=BV2 @5:><5=4CTBLAO 70AB>AC20==O ;52>F5B8@878=C C ;V:0@AL:V9 D>@>@8AB0==O C
?54V0B@VW.

5@54>7C20==O.

/8<8: A8<8 ?5@54>7C20==O <>6CBL 2:;NG0B8 A>;82VABL C 4>@>A;8E B0 ?>G0B:>25 71C465==O V ?V428I5=C 4@0BV2;82VABL 7 =0ABC?=>N A>;82VABN C 4VB59.

V:C20==O. !?5F8DVG=>3> 0=B84>BC 4> ;52>F5B8@878=C =5<0T. # 28?04:C ?>O28 A87C20==O @5:> <5=4CTBLAO A8<0B8G=0 B0 ?V4B@873;O=CB8 =5>1EV4=VABL ?@>820==O H;C=:0 G5@57 :>@>B:89 G0A ?VA;O ?@89>

>1VG=V @50:FVW.

I>:C =5@2>2>W A8AB5<8: A>;82VABL, 3>;>2=89 1V;L, ?V428I5=0 2B<;N20=VABL, A;01:VABL, 0AB5=VO, AC4<8, ?0@5AB57VO, 70?0<@>G5==O, 25@B83>, =5?@8B><=VABL, B@5<>@, 48A3527VO.

I>:C ?A8EV:8: ?>@CH5==O A=C, 71C465==O, 30;NF8=0FVW, 45?@5AVO, 03@5AVO, 157A>==O, ACWF840;L=V 4C

I>:C A5@FO: ?>A8;5=5 A5@F518BBO, B0EV:0@4VO.

I>:C >@30=V2 7>@C: ?>@CH5==O 7>@C, =5GVB:VABL 7>@C.

I>:C ?5GV=:8 B0 6>2G>282V4=8E H;OEV2: 35?0B8B.

I>:C =8@>: B0 A5G>284V;L=>W A8AB5<8: 487C@VO, 70B@8

I>:C VW A8AB5<8: 3V?5@GCB;82VABL, C B>

I>:C 48E0;L=>W A8AB5<8, >@30=V2 3@C4=>W ;:VB:8 B0 A5@54>ABV==O: 7048H:0.

I>:C H;C=:>2>-.8H:>2>3> B@0:BC: 4V0@5O, 1;N20==O, 70?>@, ACEVABL C @>BV, =C4>B0, 1V;L C 682>BV.

I>:C H:V@8 B0 ?V4H:V@=8E B:0=8=: 0=3V>=52@>B8G=89 =01@O:, ABV9:V <548:0<5=B>7=V 28A8?0==O, A25@1V6, 28A8?0==O, :@>?82O=:0.

I>:C A:5;5B=>-<07>2>W A8AB5<8, A?>;CG=>W B:0=8=8 B0 :VAB>.::

57C;LB0B8 4>A;V465=L: 71V;LH5=0 <0A0 BV;0, 2V4E8;5==O DC=:FV>=0;L=8E ?5GV=:>28E ?@>1 2V4 =>@<8.

>@CH5==O E0@GC20==O B0 >128=: ?V428I5=89 0?5B8B.

030;L=V ?>@CH5==O B0 AB0= C =01@O:.

@89>< ?@5?0@0BC A;V4 ?@8?8=8B8 C @07V ?>O28 1C4L-O:>3> V7 28I5 ?5@5;VG5=8E ?>1VG=8E 5D5:BV2 V :>;8 ?@8G8=0 9>3> @>728B:C =5 <>65 1CB8 2AB0=>2;5=0 >4=>7=0G=>.

"5@ABV.5 @>:V2.

5 70AB>A>2C20B8 ?VA;O 70:V=G5==O B5@ABV, 707=0G5=>3> =0 C?0:>2FV.

#<>28 715@V30==O.

15@V30B8 2>@83V=0;L=V9 C?0:>2FV ?@8 B530 °C C =54>ABC?=>

#?0:>2:0.

> 7 B01;5B>: C 1;VAB5@V; ?> 1 01> 2 1;VAB5@8 2=C :>@>1:C;

?> 10 B01;5B>: C 1;VAB5@V; ?> 1, 01> ?> 2, 01> ?> 3 1;VAB5@8 2 C :0@B>==C :>@>1:C.

0B53>@VO 2V4?CA:C. 57 @5F5?B0.

8@>1=8:. " \$0@<0F52B8G=89 702>4 !, #3>@I8=0.

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A020465==O 4VO;L=>ABV.

1165, 118-120, #3>@I8=0.