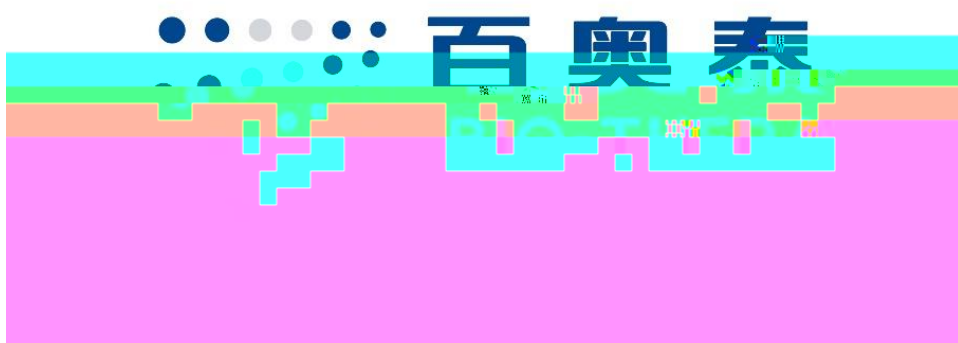

688177



1

2

“ ” “ ”

(1)

2019 12 31 BAT1406

2019 -102,262.18

(2)

2019 12 31

2019 63,651.11
1 20 1 NDA 3
1 4 I

III
III

(3)

2019 12 31 1 20 1
NDA 3 III 1 II 4
I 2019 12 31
BAT1406 BAT2094 NDA
3 5

(4)

2019 12 31

BAT1406

(5)

4

12.4.2

1

4

2019 12 31

BAT1406

BAT2094

NDA

3

4.

5

6

2019

1

$\sqrt{\quad}$ ☐

A			688177	

□ √

	11 A6	11 A6
	(8620)32203220	(8620)32203220
	db@bio-thera.com	db@bio-thera.com

2

()

2003

“ ”

2019	12	31	1	20	1
NDA	3	III	1	II	4
I					

		BAT1406	2018	8	17	CDE
2019	11		“	”		



()
1.

(1)

(2) IND

IND

Chemical Manufactureand Control,

CMC

IND

(3)

I II III
 I II III

(4)

GMP

(5)

(6)

IV

PD PK

PD

PK

PK / PD

2019 12 31 BAT1406

GMP

4.

2019 12 31 BAT1406 BAT2094 NDA

a)

2019 BAT1406
BAT1406

b)

c)

/

BU

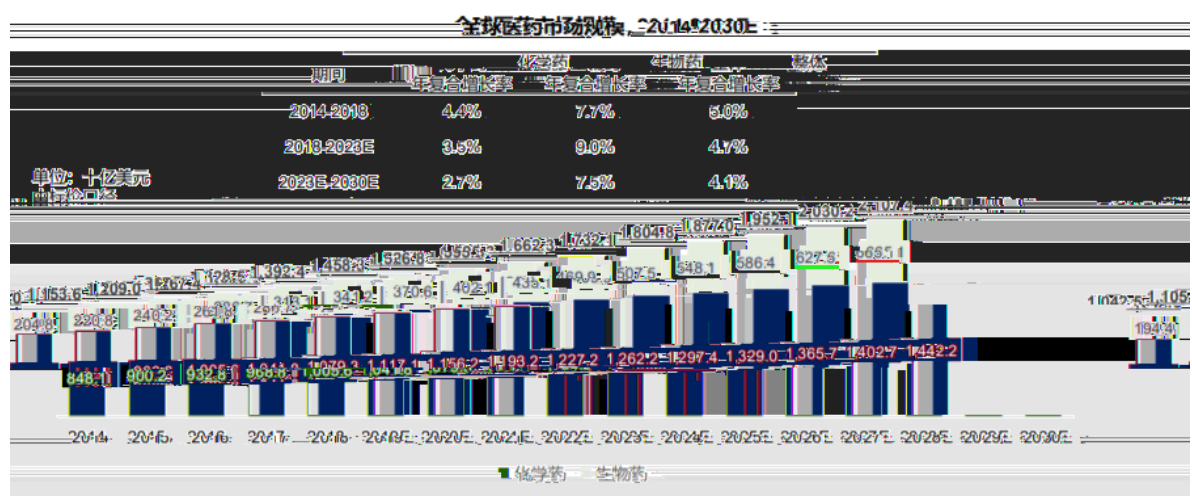
65	2014	5.9	2017	6.5
----	------	-----	------	-----

8.7%	2014	1,416
------	------	-------

2018	1,740
------	-------

2018	1.3	2030	2.1
------	-----	------	-----

0.7



	2014	2018	65
--	------	------	----

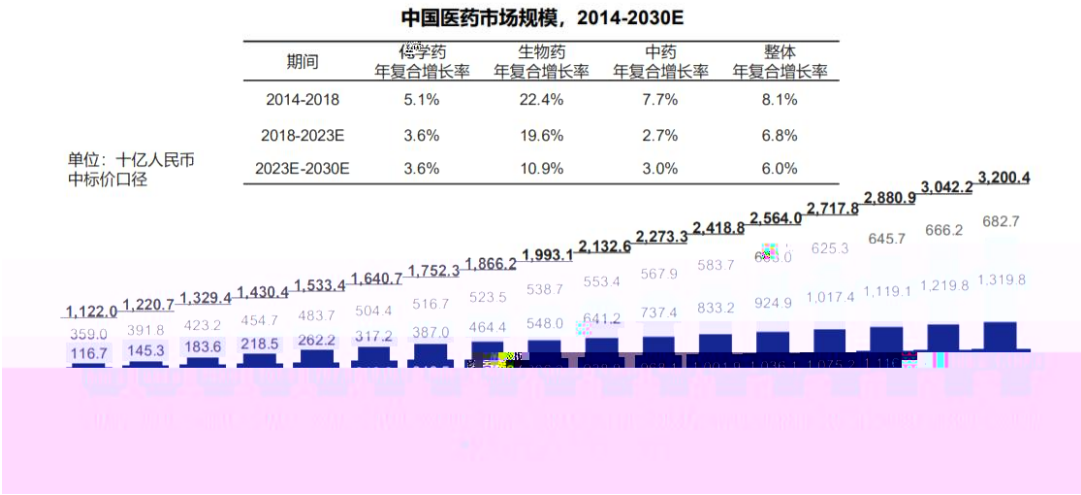
1.4	1.7	2018	11.9%
-----	-----	------	-------

2014	3.5	2017	5.3
------	-----	------	-----

2014	93	2018	174
------	----	------	-----

2014

1.1201420188.1%1.520303.2



(1)

2010 -2018

I

(2)

31

15

BAT1406

2019 11

1,290 /40mg

(3)

3

3.1 3

	2019	2018	(%)	2017
	1,014,355,689.99	1,020,759,536.09	-0.63	618,941,153.21
	700,000.00			2,008,900.00
	-1,022,621,826.46	-553,111,240.98		-235,509,536.12
	-685,554,848.14	-561,151,956.03		-233,071,215.12
	630,671,768.40	801,323,116.50	-21.30	347,552,399.73
	-597,975,664.90	-528,249,563.33		-236,682,999.32
	-2.96			
	-2.96			
%	-110.08	-774.82		-54.69

3.2

	1-3	4-6	7-9	10-12
	-	-	700,000.00	-
	-531,649,565.56	-183,451,128.83	-168,997,304.17	-138,523,827.90
	-181,472,893.15	-186,923,690.88	-173,179,173.48	-143,979,090.63
	-202,644,420.35	-156,406,583.70	-125,591,477.18	-113,333,183.67

☐ ☒

4

4.1

()						15		
()						18,254		
						0		
						0		
			(%)					
	0	159,990,270	45.18	159,990,270	0		0	
Therabio International Limited	0	47,177,729	13.32	47,177,729	0		0	
	0	23,173,326	6.54	23,173,326	0		0	
	2,400,000	21,559,471	6.09	21,559,471	0		0	

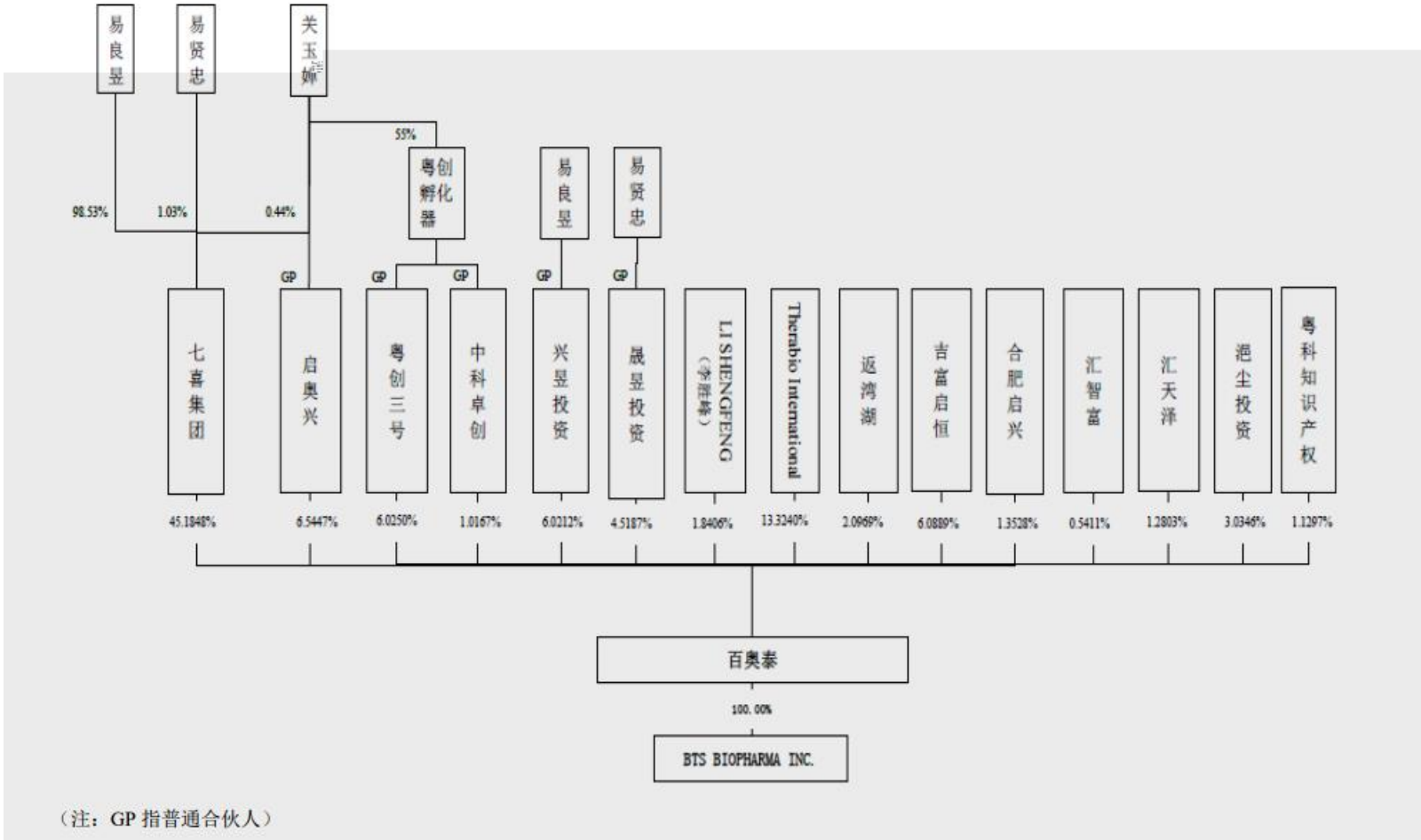
	0	21,333,332	6.03	21,333,332	0		0	
	4,680,000	21,320,002	6.02	21,320,002	0		0	
	16,000,000	16,000,000	4.52	16,000,000	0		0	
	1,000,000	10,744,802	3.03	10,744,802	0		0	
	0	7,424,586	2.10	7,424,586	0		0	
LI SHENGFENG	0	6,517,332	1.84	6,517,332	0		0	

	1. (1) (2) (3) (4) 74% 55% (5) (6) 55% (7)Therabio International LI SHENGFENG 100% (8) LI SHENGFENG 100% LI SHENGFENG (9) 100% (10) 98.8% 28.3195% (11) 38.92% 2. (1) : (2)Therabio International Limited (3)

□ √

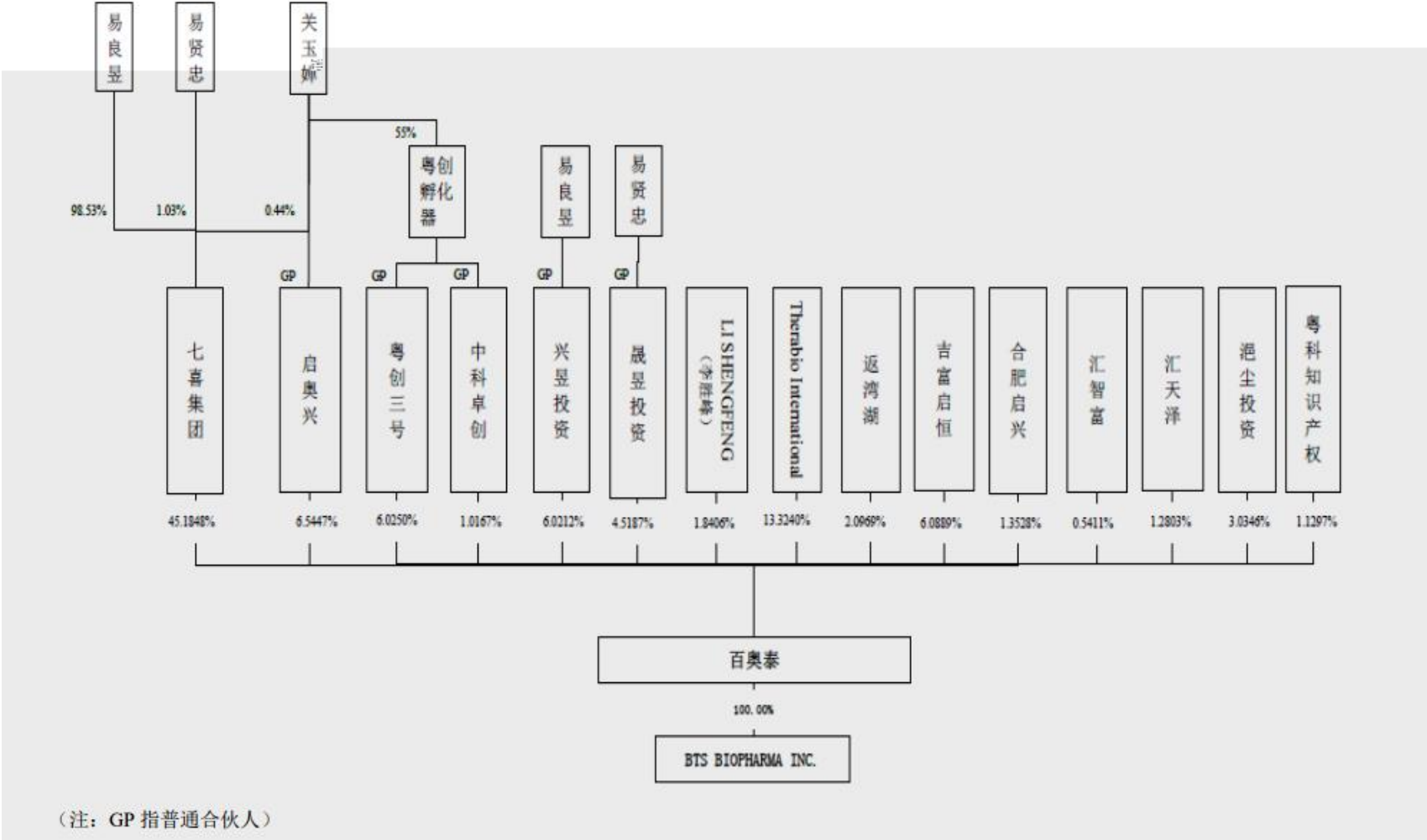
4.2

√ □



4.3

√ □



4.4 10

☐ √

5

☐ √

1

2019 1-12

70

-102,262.18

-55,311.12

46,951.06

2019

35,200.00

2

☐ √

3

√ ☐

2017 3 31

22

23

24

2017 5 2

37

2019 1 1

(“

) ”

44

4

☐ √

5

√ ☐