
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of **May 2023**

Commission File Number: **001-39034**

BELLUS HEALTH INC.

(Name of registrant)

**275 Armand-Frappier Blvd.
Laval, Québec
H7V 4A7
Canada**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F

Form 40-F

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BELLUS Health Inc.

Date: May 11, 2023

By: /s/ Ramzi Benamar

Name: Ramzi Benamar

Title: Chief Financial Officer

Form 6-K Exhibit Index

Exhibit Number	Document Description
99.1	Condensed Consolidated Interim Financial Statements (Unaudited) for the periods ended March 31, 2023 and 2022.
99.2	Management's Discussion and Analysis for the three-month period ended March 31, 2023.
99.3	Form 52-109F2 Certification of Interim Filings – CEO.
99.4	Form 52-109F2 Certification of Interim Filings – CFO.

Condensed Consolidated Interim Financial Statements of
(Unaudited)

BELLUS HEALTH INC.

Periods ended March 31, 2023 and 2022
(In thousands of United States dollars)

BELLUS HEALTH INC.

Condensed Consolidated Interim Financial Statements
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars)

Condensed Consolidated Interim Financial Statements

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BELLUS HEALTH INC.Condensed Consolidated Interim Statements of Financial Position
(Unaudited)

As at March 31, 2023 and December 31, 2022

(In thousands of United States dollars)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents (note 4)	\$ 85,375	\$ 87,250
Short-term investments (note 4)	227,614	249,807
Trade and other receivables	990	663
Research tax credit receivable	1,052	980
Prepaid expenses and other assets	12,682	17,193
Total current assets	<u>327,713</u>	<u>355,893</u>
Non-current assets:		
Right-of-use asset	1,202	1,306
Other assets	362	340
Deferred tax asset	166	181
In-process research and development asset (note 5)	50,100	50,100
Total non-current assets	<u>51,830</u>	<u>51,927</u>
Total Assets	<u>\$ 379,543</u>	<u>\$ 407,820</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade and other payables	\$ 9,440	\$ 15,525
Lease liability	365	351
Total current liabilities	<u>9,805</u>	<u>15,876</u>
Non-current liabilities:		
Lease liability	834	932
Total non-current liabilities	<u>834</u>	<u>932</u>
Total Liabilities	<u>10,639</u>	<u>16,808</u>
Shareholders' equity:		
Share capital (note 6 (a))	977,657	977,320
Other equity (notes 6 (b) (i))	48,847	46,232
Deficit	(666,898)	(641,838)
Accumulated other comprehensive income	9,298	9,298
Total Shareholders' Equity	<u>368,904</u>	<u>391,012</u>
Commitments and contingencies (note 9)		
Subsequent event (note 12)		
Total Liabilities and Shareholders' Equity	<u>\$ 379,543</u>	<u>\$ 407,820</u>

See accompanying notes to unaudited condensed consolidated interim financial statements.

BELLUS HEALTH INC.Condensed Consolidated Interim Statements of Loss and Other Comprehensive Loss
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data)

	Three-month periods ended	
	March 31,	
	2023	2022
Revenues	\$ 3	\$ 4
Expenses:		
Research and development	22,408	11,380
Research tax credits	(73)	(126)
	22,335	11,254
General and administrative	5,392	4,050
Total operating expenses	27,727	15,304
Loss from operating activities	(27,724)	(15,300)
Finance income	3,221	1,255
Finance costs	(538)	(282)
Net finance income (note 7)	2,683	973
Loss before income taxes	(25,041)	(14,327)
Income taxes	19	25
Net loss and total comprehensive loss for the period	\$ (25,060)	\$ (14,352)
Net loss per share (note 8)		
Basic and diluted	\$ (0.20)	\$ (0.13)

See accompanying notes to unaudited condensed consolidated interim financial statements.

BELLUS HEALTH INC.Condensed Consolidated Interim Statements of Changes in Shareholders' Equity
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars)

	Share capital (note 6 (a))	Other equity	Deficit	Accumulated other comprehensive income	Total
Balance, December 31, 2022	\$ 977,320	\$ 46,232	\$ (641,838)	\$ 9,298	\$ 391,012
Total comprehensive loss for the period:					
Net loss and comprehensive loss	—	—	(25,060)	—	(25,060)
Total comprehensive loss for the period	<u>—</u>	<u>—</u>	<u>(25,060)</u>	<u>—</u>	<u>(25,060)</u>
Transactions with shareholders, recorded directly in shareholders' equity:					
Issued upon stock options exercise (note 6 (b) (i))	337	(317)	—	—	20
Stock-based compensation (note 6 (b) (i))	—	2,932	—	—	2,932
Balance, March 31, 2023	<u>\$ 977,657</u>	<u>\$ 48,847</u>	<u>\$ (666,898)</u>	<u>\$ 9,298</u>	<u>\$ 368,904</u>
	Share capital (note 6 (a))	Other equity	Deficit	Accumulated other comprehensive income	Total
Balance, December 31, 2021	\$ 799,391	\$ 37,664	\$ (554,324)	\$ 9,298	\$ 292,029
Total comprehensive loss for the period:					
Net loss and comprehensive loss	—	—	(14,352)	—	(14,352)
Total comprehensive loss for the period	<u>—</u>	<u>—</u>	<u>(14,352)</u>	<u>—</u>	<u>(14,352)</u>
Transactions with shareholders, recorded directly in shareholders' equity:					
Issued upon stock options exercise (note 6 (b) (i))	624	(541)	—	—	83
Stock-based compensation (note 6 (b) (i))	—	2,033	—	—	2,033
Balance, March 31, 2022	<u>\$ 800,015</u>	<u>\$ 39,156</u>	<u>\$ (568,676)</u>	<u>\$ 9,298</u>	<u>\$ 279,793</u>

See accompanying notes to unaudited condensed consolidated interim financial statements.

BELLUS HEALTH INC.Condensed Consolidated Interim Statements of Cash Flows
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars)

	Three-month periods ended March 31,	
	2023	2022
Cash flows from (used in) operating activities:		
Net loss for the period	\$ (25,060)	\$ (14,352)
Adjustments for:		
Depreciation	104	72
Stock-based compensation	2,932	2,033
Net finance income, excluding realized effect of foreign exchange on operating assets and liabilities	(2,685)	(973)
Other items	(1)	11
Changes in operating assets and liabilities		
Trade and other receivables	(328)	(164)
Research tax credits receivable	(71)	(126)
Prepaid expenses and other assets	3,909	(1,415)
Deferred tax asset	15	20
Trade and other payables	(5,917)	(93)
Current income tax liabilities	—	5
	<u>(27,102)</u>	<u>(14,982)</u>
Cash flows from (used in) financing activities:		
Payment of share issue costs related to equity offerings	—	(746)
Issuance of common shares – Proceeds received from exercise of stock options	20	83
Payment of deferred financing costs	(125)	(142)
Lease liability – principal repayments	(113)	(52)
Interest paid	(1)	(5)
	<u>(219)</u>	<u>(862)</u>
Cash flows from (used in) investing activities:		
Purchases of short-term investments	(30,765)	(22,500)
Sales of short-term investments	54,566	35,072
Interest received	1,476	72
	<u>25,277</u>	<u>12,644</u>
Net decrease in cash and cash equivalents	(2,044)	(3,200)
Cash and cash equivalents, beginning of period	87,250	150,078
Effect of foreign exchange on cash and cash equivalents	169	277
Cash and cash equivalents, end of period	<u>\$ 85,375</u>	<u>\$ 147,155</u>
Supplemental cashflow disclosure:		
Non-cash transactions:		
Share issue costs related to equity offerings, in Trade and other payables	\$ —	\$ 25
Ascribed value related to issuance of common shares upon stock options exercise (note 6 (b) (i))	317	541
Value of DSUs in Prepaid expenses (note 6 (b) (ii))	<u>31</u>	<u>34</u>

See accompanying notes to unaudited condensed consolidated interim financial statements.

BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except for share data, unless otherwise noted)

1. Reporting entity:

BELLUS Health Inc. (“BELLUS Health” or the “Company”) is a clinical-stage biopharmaceutical company working to better the lives of patients suffering from persistent cough, starting with the development of camlipixant (BLU-5937) for the treatment of refractory chronic cough (“RCC”). Camlipixant is a highly selective second-generation antagonist of the P2X3 receptor, a clinically validated target to treat cough hypersensitivity. The Company is domiciled in Canada. The address of the Company’s registered office is 275 Armand-Frappier Blvd., Laval, Quebec, Canada H7V 4A7. BELLUS Health’s common shares trade on the Nasdaq Capital Market (“Nasdaq”) and on the Toronto Stock Exchange (“TSX”) both under the symbol BLU.

These condensed consolidated interim financial statements include the accounts of BELLUS Health Inc. and its subsidiaries.

The annual consolidated financial statements of the Company as at and for the year ended December 31, 2022 are available on our web site at www.bellushealth.com, on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar.

2. Basis of preparation:**(a) Statement of compliance:**

These condensed consolidated interim financial statements have been prepared in accordance with International Accounting Standard (IAS) 34, *Interim Financial Reporting* of International Financial Reporting Standards (“IFRS”). The condensed consolidated interim financial statements do not include all the information required for full annual consolidated financial statements and should be read in conjunction with the annual consolidated financial statements as at and for the year ended December 31, 2022. These condensed consolidated interim financial statements have not been reviewed by the Company’s auditors.

These condensed consolidated interim financial statements for the three-month period ended March 31, 2023 were approved by the Board of Directors on May 12, 2023.

(b) Use of estimates and judgements:

The preparation of the condensed consolidated interim financial statements in accordance with IFRS requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. The reported amounts and note disclosures reflect management’s best estimates of the most probable set of economic conditions and planned course of actions. Actual results may differ from these estimates.

BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

2. Basis of preparation (continued):

(b) Use of estimates and judgements (continued):

In preparing these condensed consolidated interim financial statements, the significant judgements made by management in applying the Company's accounting policies and key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31, 2022.

(c) Functional and presentation currency:

Items included in the condensed consolidated interim financial statements of the Company are measured using the currency of the primary economic environment in which the Company operates (the functional currency). These condensed consolidated interim financial statements are presented in United State dollars ("USD"), which is the Company's functional and presentation currency for all periods presented.

3. Significant accounting policies and basis of measurement:

The accounting policies and basis of measurement applied in these condensed consolidated interim financial statements are the same as those applied by BELLUS Health in its consolidated financial statements for the year ended December 31, 2022.

BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

4. Cash, cash equivalents and short-term investments:

Cash, cash equivalents and short-term investments consist of cash balances with banks and short-term investments:

	March 31, 2023	December 31, 2022
Cash balances with banks	\$ 8,581	\$ 12,906
Short-term investments with initial maturities of three months or less or that can be withdrawn on demand:		
Savings accounts and term deposits, yielding interest at 2.85% to 4.65% as at March 31, 2023 (December 31, 2022 – 2.56% to 4.25%)	76,794	74,344
Cash and cash equivalents	85,375	87,250
Short-term investments with initial maturities greater than three months:		
Term deposits, yielding interest at 3.60% to 4.21% as at March 31, 2023 (December 31, 2022 – 3.60% to 4.21%)	55,407	54,875
Term deposits issued of CAD\$43,228, yielding interest at 4.20% to 5.65% as at March 31, 2023 (December 31, 2022 – (CAD \$30,478), 4.20% to 5.65%)	31,976	22,486
Bearer deposit notes, yielding interest at 3.62% to 5.20% as at March 31, 2023 (December 31, 2022 – 0.40% to 5.20%)	113,692	146,108
T-Bill, yielding interest at 3.13% as at March 31, 2023 (December 31, 2022 –3.13%)	26,539	26,338
Short-term investments	227,614	249,807
Cash, cash equivalents and short-term investments	<u>\$ 312,989</u>	<u>\$ 337,057</u>

5. In-process research and development asset:

As at March 31, 2023 and December 31, 2022, the aggregate carrying value of the in-process research and development (“IPR&D”) asset related to BLU-5937 amounted to \$50,100. The IPR&D asset related to BLU-5937 is accounted for as an indefinite-lived intangible asset until the project, currently in its clinical phase, is completed or abandoned, at which point it will be amortized or impaired, respectively.

BELLUS HEALTH INC.Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

6. Shareholders' equity:

(a) Share capital:

Changes in issued and outstanding common shares for the periods ended March 31, 2023 and 2022 were as follows:

	Number	Dollars
Balance, December 31, 2022	126,567,121	\$ 977,320
Issued upon stock option exercises (note 9 (b) (i))	117,282	337
Balance, March 31, 2023	<u>126,684,403</u>	<u>\$ 977,657</u>
	Number	Dollars
Balance, December 31, 2021	106,390,361	\$ 799,391
Issued upon stock option exercises (note 6 (b) (i))	354,070	624
Balance, March 31, 2022	<u>106,744,431</u>	<u>\$ 800,015</u>

"At-the-market" sales agreements

2022 ATM Sales Agreement

On November 14, 2022, the Company entered into an "at-the-market" ("ATM") sales agreement (the "2022 ATM Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company may from time to time, sell its common shares, through ATM distributions with Jefferies acting as sales agent (the "Agent") for aggregate gross proceeds of up to \$80,000, including sales made directly on the Nasdaq or on any other existing trading market for the common shares in the United States. No common shares will be offered or sold in Canada.

BELLUS HEALTH INC.Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

6. Shareholders' equity (continued):

(a) Share capital (continued):

"At-the-market" sales agreements (continued):

2022 ATM Sales Agreement (continued)

The ATM expires no later than the end of the 25-month period starting August 26, 2022 and requires the Company to pay to the Agent a commission of up to 3% of the gross proceeds of any common shares sold. Subject to the terms and conditions of the Sales Agreement, the Agent will use its commercially reasonable efforts to sell the common shares from time to time, based upon the Company's instructions. The Company has no obligation to sell any of the common shares and may at any time suspend sales under the Sales Agreement. The Company and the Agent may terminate the 2022 ATM Sales Agreement, at any time, in accordance with its terms. Under the terms of the 2022 ATM Sales Agreement, the Company has provided the Agent with customary indemnification rights.

During the three-month period ended March 31, 2023, no common shares were sold under the 2022 ATM program. As a result of the announcement of the BELLUS Health acquisition by GSK subsequent to the reporting period (refer to note 12), total costs incurred to register the Sales Agreement, previously recorded as deferred financing costs and classified as prepaids and other assets in the consolidated statement of financial position, were impaired in the condensed consolidated interim statement of loss and other comprehensive loss and are presented in Finance costs (refer to note 7), as it is not probable that the ATM will be used in the future.

(b) Share-based payment arrangements:

(i) Stock Option Plan:

Changes in outstanding stock options issued under the Stock Option Plan for the three-month periods ended March 31, 2023 and 2022 were as follows:

	Number	Weighted average exercise price ⁽¹⁾
Balance, December 31, 2022	10,218,723	\$ 5.38
Granted ⁽²⁾	2,133,875	7.50
Exercised ⁽³⁾	(168,556)	2.50
Forfeited	(26,000)	9.30
Balance, March 31, 2023	<u>12,158,042</u>	<u>\$ 5.79</u>

BELLUS HEALTH INC.Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

6. Shareholders' equity (continued):

(b) Share-based payment arrangements (continued):

(i) Stock Option Plan (continued):

	Number	Weighted average exercise price ⁽¹⁾
Balance, December 31, 2021	7,774,833	\$ 3.97
Granted ^{(4), (5)}	3,335,000	\$ 6.94
Exercised ⁽⁶⁾	(436,388)	\$ 1.46
Forfeited	(56,000)	\$ 4.34
Balance, March 31, 2022	<u>10,617,445</u>	<u>\$ 5.01</u>

(1) USD equivalent of stock options granted in CAD is presented at the closing rate of the corresponding year.

(2) 2,133,875 stock options were granted on March 21, 2023, having an exercise price of \$7.50; 1,313,875 stock options were granted to key management personnel and 820,000 were granted to other employees.

(3) Of the stock options exercised, 117,282 common shares were issued, and 51,274 stock options were returned to the Company and cancelled as a result of the cashless exercise feature provided in the Company's stock option plan.

(4) 2,945,000 stock options were granted on February 23, 2022, having an exercise price of \$7.01; 2,320,000 stock options were granted to key management personnel and 625,000 were granted to other employees.

(5) 390,000 stock options were granted to key management personnel on March 23, 2022, having an exercise price of \$6.38.

(6) Of the stock options exercised, 354,070 common shares were issued, and 82,318 stock options were returned to the Company and cancelled as a result of the cashless exercise feature provided in the Company's stock option plan.

BELLUS HEALTH INC.Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

6. Shareholders' equity (continued):

(b) Share-based payment arrangements (continued):

(i) Stock Option Plan (continued):

The following table summarizes information about stock options outstanding and exercisable as at March 31, 2023:

Exercise price/share	Options outstanding		Options exercisable Number
	Number	Weighted average years To expiration	
Stock options granted in USD			
\$3.83	50,000	8.0	20,000
\$3.92	42,000	8.1	2,000
\$4.36	1,320,800	7.9	500,600
\$6.38	390,000	9.0	78,000
\$7.01	2,902,500	8.9	564,500
\$7.50	2,133,875	10.0	—
\$7.04	160,000	8.6	32,000
\$7.85	220,000	9.1	—
\$9.00	198,500	9.6	—
\$9.39	180,000	9.3	—
Stock options granted in CAD ⁽¹⁾			
\$0.80 (CAD \$1.08)	561,868	4.1	561,868
\$0.93 (CAD \$1.26)	980,280	4.9	980,280
\$1.12 (CAD \$1.51)	41,667	4.6	41,667
\$1.52 (CAD \$2.05)	8,333	5.3	—
\$2.32 (CAD \$3.14)	162,000	7.6	63,000
\$2.65 (CAD \$3.58)	28,000	7.4	10,000
\$2.98 (CAD \$4.03)	28,611	2.9	28,611
\$3.05 (CAD \$4.12)	416,000	7.7	164,000
\$3.22 (CAD \$4.36)	861,386	5.9	673,609
\$6.21 (CAD \$8.39)	512,222	6.6	307,333
\$10.29 (CAD \$13.91)	895,000	7.0	358,000
\$10.89 (CAD \$14.72)	65,000	7.1	26,000
	<u>12,158,042</u>	<u>7.9</u>	<u>4,411,468</u>

(1) USD equivalent of stock options granted in CAD is presented at the closing rate.

BELLUS HEALTH INC.Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

6. Shareholders' equity (continued):

(b) Share-based payment arrangements (continued):

(i) Stock Option Plan (continued):

Stock-based compensation:

For the three-month period ended March 31, 2023, the Company recorded a stock-based compensation expense related to the stock option plan (excluding compensation under the DSU plans) in the amount of \$2,932 in the condensed consolidated interim statement of loss and other comprehensive loss; of this amount, \$1,369 is presented in Research and development expenses and \$1,563 is presented in General and administrative expenses (\$2,033 for the corresponding period of the previous year, \$699 and \$1,334 respectively presented in Research and development and General and administrative expenses).

The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes pricing model. Expected volatility is estimated by considering historic average share price volatility for a period commensurate with the expected life. The weighted average assumptions for stock options granted during the three-month periods ended March 31, 2023 and 2022 were as follows:

	2023	2022
Weighted average fair value of stock options at grant date	\$ 6.18	\$ 5.13
Weighted average share price	\$ 7.50	\$ 6.94
Weighted average exercise price	\$ 7.50	\$ 6.94
Risk-free interest rate	3.54%	1.96%
Expected volatility	99%	100%
Expected life in years	7	7
Expected dividend yield	Nil	Nil

Dividend yield was excluded from the calculation since it is the present policy of the Company to retain all earnings to finance operations and future growth.

BELLUS HEALTH INC.Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

6. Shareholders' equity (continued):

(b) Share-based payment arrangements (continued):

(ii) Deferred share unit (DSU) plan:

Changes in the number of units for the three-month periods ended March 31, 2023 and 2022 were as follows:

Number of units	2023	2022
Balance, end of year	341,273	311,065
Balance of DSU liability, included in Trade and other payables ⁽¹⁾	\$ 2,451	\$ 2,149

⁽¹⁾ Balance of DSU liability as at December 31, 2022 amounted to \$2,790.

The stock-based compensation net (recovery) expense related to DSU plan recorded in the condensed consolidated interim statement of loss and other comprehensive loss for the three-month period ended March 31, 2023 amounted to \$(283), presented in General and administrative expenses (net recovery of \$(310) for the corresponding period of the previous year).

BELLUS HEALTH INC.Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

7. Net finance income:

Finance income and Finance costs for the periods ended March 31, 2023 and 2022 were attributed as follows:

	2023	2022
Interest income	\$ 3,130	\$ 296
Foreign exchange gain	91	959
Finance income	<u>3,221</u>	<u>1,255</u>
Interest expense on lease liability	(19)	(9)
Interest and bank charges	(1)	(5)
Impairment of deferred financing costs	(518)	—
Realized loss on sale of bearer deposit notes prior to maturity	—	(268)
Finance costs	<u>(538)</u>	<u>(282)</u>
Net finance income	<u>\$ 2,683</u>	<u>\$ 973</u>

BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

8. Loss per share:

	Three-month periods ended March 31,	
	2023	2022
Basic weighted average number of common shares outstanding	<u>126,581,582</u>	<u>106,489,413</u>
Basic and diluted loss per share	<u>\$ (0.20)</u>	<u>\$ (0.13)</u>

Excluded from the calculation of the diluted loss per share for the three-month periods ended March 31, 2023 and 2022 is the impact of all stock options granted under the stock option plan, as they would be anti-dilutive.

Stock options granted under the stock option plan could potentially be dilutive in the future.

9. Commitments and contingencies:**(a) Contracts in the normal course of business:**

The Company enters into contracts in the normal course of business, including for research and development activities, consulting and other services.

As at March 31, 2023, the Company has commitments for expenditures related to contracts with service providers for research and development activities of approximately \$181,295 (approximately \$184,744 as at December 31, 2022), of which \$51,816 is expected to be payable in 2023, \$60,724 in 2024, \$51,456 in 2025 and \$17,299 in 2026.

BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

(b) Contingencies:

On July 6, 2022, a Company stockholder, Jason Gallanti (the “Canadian Plaintiff”), filed a statement of claim before the Ontario Superior Court of Justice against the Company alleging negligent misrepresentation and claims under the Ontario Securities Act (“OSA”) and equivalent provincial securities legislation relating to disclosures concerning the Company’s Phase 2a RELIEF trial. The Canadian Plaintiff seeks certification of the action as a class proceeding on behalf of those who purchased the Company’s stock on the TSX, leave to pursue statutory claims under the OSA, compensatory damages, prejudgment and post-judgment interest, and costs of the action. Following the dismissal of the Plaintiff’s claim on September 22, 2022, the Canadian Plaintiff has filed, on January 27, 2023, a motion to discontinue his claim and the parties are awaiting for the order approving the discontinuance to be entered and issued.

BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

9. Commitments and contingencies (continued):

(b) Contingencies (continued):

No provision has been made in the financial statements for the resolution of the above matter. Resolution of litigation could have an effect on the Company's financial statements in the period that a determination is made, however, in management's opinion, this litigation matter is not currently projected to have a material adverse effect on the Company's financial position.

10. Related party transactions:

(a) There is no single ultimate controlling party.

(b) Dr. Francesco Bellini, Chairman of the Board of Directors, provides ongoing advisory services to the Company under the terms of a consulting and services agreement between the Company and Picchio International, wholly-owned by Dr. Francesco Bellini and his spouse. The agreement has a one-year term and shall renew for successive one-year terms. The Company recorded fees and expenses of \$71 and \$75 (CAD \$95 for both periods) under the consulting and services agreement for the periods ended March 31, 2023 and 2022, respectively.

BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

(c) Key management personnel:

The Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, the Chief Scientific Officer, the Chief Operating Officer, the Chief Business Officer and Directors of BELLUS Health are considered key management personnel.

The aggregate compensation to key management personnel of the Company for the periods ended March 31, 2023 and 2022 is set out below:

	Three-month periods ended	
	March 31,	
	2023	2022
Short-term benefits	\$ 1,064	\$ 966
Stock-based compensation (recovery) expense – DSU plan	(283)	(310)
Stock option plan expense	1,980	1,597
	<u>\$ 2,761</u>	<u>\$ 2,253</u>

BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)
(Unaudited)

Periods ended March 31, 2023 and 2022

(In thousands of United States dollars, except per share data, unless otherwise noted)

11. Financial instruments:

Carrying values and fair values:

Fair value estimates are made as of a specific point in time, using available information about the financial instrument. These estimates are subjective in nature and may not be determined with precision. A three-tier fair value hierarchy prioritizes the inputs used in measuring fair value.

There was no financial asset or liability fair valued on a recurring basis as at March 31, 2023 and December 31, 2022.

For its financial assets and liabilities measured at amortized cost as at March 31, 2023, the Company has determined that the carrying value of its short-term financial assets and liabilities approximates their fair value because of the relatively short periods to maturity of these instruments.

12. Subsequent event:

On April 18, 2023, GSK plc (“GSK”) and BELLUS Health announced that they have entered into an agreement under which GSK will acquire the Company for \$14.75 per share of common stock in cash representing an approximate total equity value of \$2.0 billion.

Under the terms of the agreement, the acquisition will be effected through a Plan of Arrangement pursuant to the Canada Business Corporations Act in which the outstanding shares of BELLUS Health will be acquired by the GSK in consideration of \$14.75 per share in cash. Subject to customary conditions, including court approval, the approval of the acquisition by at least 66.67% of the votes cast at a meeting of BELLUS Health's shareholders and a majority of the votes cast by non-interested shareholders at such meeting, and approval by the appropriate regulatory agencies, the transaction is expected to close in the third quarter of 2023 or earlier.

BELLUS Health's Board of Directors has unanimously recommended that the Company's shareholders vote in favour of the approval of the acquisition.

MANAGEMENT’S DISCUSSION AND ANALYSIS

This Management’s Discussion and Analysis (“MD&A”) provides a review of BELLUS Health Inc.’s operations and financial performance for the three-month period ended March 31, 2023. In this MD&A, unless the context otherwise requires, the terms “BELLUS Health”, “Company”, “we”, “us”, and “our” refer to BELLUS Health Inc. This document should be read in conjunction with our unaudited condensed consolidated interim financial statements for the three-month period ended March 31, 2023, as well as our audited consolidated financial statements for the year ended December 31, 2022.

We prepare our condensed consolidated interim financial statements in accordance with the International Accounting Standard (“IAS”) 34, *Interim Financial Reporting* of International Financial Reporting Standards (“IFRS”), as issued by the International Accounting Standards Board (“IASB”). The condensed consolidated interim financial statements and MD&A for the three-month period ended March 31, 2023 have been reviewed by our Audit Committee and approved by our Board of Directors. This MD&A was prepared by management with information available as of May 12, 2023. Additional information regarding our business and other matters, including related-party transactions, contractual obligations, financial risk management, disclosure controls and procedures, internal control over financial reporting, and risks and uncertainties, can be found in our Annual Report and Annual Information Form for the year ended December 31, 2022, as well as in our annual report on Form 40-F filed with the U.S. Securities and Exchange Commission and our other public filings, which are available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar. Please also refer to the “Risks and Uncertainties” section, which can be found below.

This document contains forward-looking statements, which are qualified by reference to, and should be read together with the “Forward-Looking Statements” cautionary notice, which can be found below.

All currency figures reported in the condensed consolidated interim financial statements and in this document are in U.S. dollars, unless otherwise specified.

FORWARD-LOOKING STATEMENTS

Certain statements contained in this MD&A may constitute “forward-looking information” within the meaning of applicable securities laws in Canada and “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended (collectively, “forward-looking statements”), which involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, objectives and strategies to achieve those objectives, as well as statements with respect to our beliefs, targets, expectations, anticipations, estimates or intentions. In some cases, you can identify forward-looking statements by terminology such as “believe”, “may”, “estimate”, “continue”, “anticipate”, “intend”, “should”, “plan”, “expect”, “predict”, “potential”, “could”, “assume”, “project”, “guidance” or the negative of these terms or other similar expressions, although not all forward-looking statements include such words. These statements reflect current expectations of management regarding future events and operating performance and speak only as of the date of this MD&A. The statements we make regarding the following matters are forward-looking by their nature and are based on certain of the assumptions noted below:

- our aim to close the arrangement with GSK;
- the risk that a condition to closing of the arrangement may not be satisfied, the risk that any required shareholder, court or applicable regulatory approvals for the arrangement may not be obtained or be obtained subject to conditions that are not anticipated, the failure to realize the anticipated benefits of the transaction, the occurrence of any event that could give rise to termination of the transaction, and potential litigation in connection with the transaction or other settlements or investigations that may affect the timing or occurrence of the transaction or result in significant costs of defense, indemnification and liability.
- our aim to develop, obtain FDA approval for, and commercialize camlipixant (BLU-5937) for the treatment of refractory chronic cough (“RCC”) and other cough hypersensitization disorders;
- our aim to complete our CALM Phase 3 clinical trials as designed, including our expectations to release topline results from CALM-1 and CALM-2 in the second half of 2024 and in 2025, respectively;
- our expectations to continue the development of the once-daily (“QD”) dosing, extended-release (“ER”) formulation of camlipixant;
- our aim to complete additional non-clinical toxicology studies and Phase 1 clinical trials supporting a new drug application (“NDA”) filing for camlipixant;
- our aim to further explore the potential of camlipixant for the treatment of other afferent hypersensitization-related conditions;
- our aim to complete all non-clinical and clinical pharmacology activities with camlipixant necessary to support an NDA filing;

- our expectations with respect to the timing and cost of the research and development activities of camlipixant;
- our aim to complete the validation of the VitaloJAK for cough frequency measurement in our studied patient population to the satisfaction of relevant regulatory agencies;
- the function, potential benefits, tolerability profile and clinical activity of our product candidates, including camlipixant, including with respect to the patient population studied, pricing and labeling;
- our expectations with respect to pre-commercialization activities related to the commercial launch of camlipixant, if approved;
- our expectations regarding the potential development of a QD dosing regimen of camlipixant utilizing an extended-release formulation;
- our expectations regarding our ability to arrange for and scale up the manufacturing of camlipixant to reach commercial scale, if approved;
- our estimates and assessment of the potential markets (including size) for our product candidates;
- our expectations regarding coverage, reimbursement and pricing and acceptance of our product candidates by the market, if approved, including pricing comparisons with other P2X3 receptor antagonists;
- our estimates and projections regarding the size of the total addressable global RCC market and associated P2X3 receptor revenue potential;
- the benefits and risks of our product candidates as compared to others;
- our aim to obtain regulatory approval to market our product candidates;
- our expectations with respect to the cost of preclinical and non-clinical studies, clinical trials and potential commercialization of our product candidates, including camlipixant;
- our expectation of the continued listing of the common shares on the TSX and Nasdaq;
- our current and future capital requirements and anticipated sources of financing or revenue;
- our expectations regarding the ongoing COVID-19 pandemic and its impact on our business;
- our expectation with respect to the cost and availability of raw materials, equipment, labor and transportation;
- our expectations regarding the protection of our intellectual property and our ability to secure patent term extensions for our intellectual property;
- our business strategy; and
- our development and partnership plans and objectives.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements.

Conclusions, forecasts and projections set out in forward-looking information are based on our current objectives and strategies and on expectations and estimates and other factors and assumptions that we believe to be reasonable at the time applied but may prove to be incorrect. These include, but are not limited to:

- our ability to close the arrangement with GSK and the timeline expected in respect thereof;
- the function, potential benefits, effectiveness and safety of camlipixant;
- the accuracy of our belief that our selective P2X3 receptor antagonist may have an improved tolerability profile compared to the most advanced P2X3 receptor antagonist in development, Merck & Co.'s gefapixant;
- our progress, timing and costs related to the development, completion and potential commercialization of our product candidate;
- our estimates and projections regarding our industry;
- the market acceptance of our product candidate, if approved;
- the future success of current research and development activities;
- our achievement of development and commercial milestones, including forecasted preclinical and non-clinical studies and clinical trial milestones within the anticipated timeframe;
- our reliance on third parties to conduct preclinical and non-clinical studies and clinical trials for camlipixant;
- the accuracy of the timelines and cost estimates related to our preclinical, non-clinical and clinical programs;
- the successful development of a QD dosing with extended-release formulation for camlipixant;
- our ability to achieve intended order of market entry of camlipixant relative to other P2X3 receptor antagonists;
- the accuracy of our findings of statistically significant interaction between baseline cough frequency and treatment benefit, realization of the intended benefits, acceptability to regulatory agencies and impact of our enrichment strategy;
- continuing feedback and discussions with the FDA and other regulatory authorities regarding the design of the CALM Phase 3 program;
- the accuracy of our estimates and projections regarding potential pricing for camlipixant, including parity to other P2X3 receptor antagonists;
- the accuracy of our estimates and projections regarding the size of the total addressable global RCC market and associated P2X3 receptor revenue potential;
- the capacity of our primary supply chain to produce the required clinical supplies to support a Phase 3 clinical program in RCC within the anticipated timeframe, and the absence of further global supply chain disruptions with respect to such required clinical supplies, including those that may be caused by the ongoing COVID-19 pandemic;
- the absence of interruption or delays in the operations of our suppliers of components or raw materials, contract research organizations or other third parties with whom we engage, whether as a result of disruptions caused by the ongoing COVID-19 pandemic or otherwise;

- the accuracy of our expectations regarding labeling indication for camlipixant in RCC and the potential to expand the use of P2X3 receptor antagonists to all RCC patients;
- the absence of material deterioration in general business and economic conditions, including the impact on the economy and financial markets of the war in Ukraine, and the ongoing COVID-19 pandemic and other health risks;
- the effect of macroeconomic conditions, including rising interest rates and inflation, on our business operations;
- the effectiveness of COVID-19 containment efforts, including the roll-out of vaccination programs, the effectiveness of vaccines against variant strains of COVID-19 (including the Omicron variants) and the gradual recovery of global environment and global economic conditions;
- the impact of COVID-19 on participant enrollment;
- the risks of delays and inability to complete clinical trials due to difficulties enrolling participants, including, but not limited to, as a result of the ongoing COVID-19 pandemic;
- the receipt of regulatory and governmental approvals to continue with research and development projects and timing thereof;
- the availability of tax credits and financing for research and development projects, and the availability of financing on favorable terms;
- our expectations regarding our status as a passive foreign investment company;
- the accuracy of our estimates regarding future financing and capital requirements and expenditures;
- the achievement of our forecasted cash burn rate;
- the sufficiency and validity of our intellectual property rights;
- our ability to secure, maintain and protect our intellectual property rights, and to operate without infringing on the proprietary rights of others or having third parties circumvent the rights owned or licensed by us;
- our ability to source and maintain licenses from third-party owners on acceptable terms and conditions;
- the risk of patent-related litigation;
- the absence of significant changes in Canadian dollar-U.S. dollar and other foreign exchange rates or significant variability in interest rates;
- the absence of material changes in market competition and accuracy of our assumptions and projections regarding profile and market dynamic amongst more selective agents;
- our ability to attract and retain skilled staff;

- our ability to maintain ongoing relations with employees and business partners, suppliers and other third parties;
- the accuracy of the market research, third-party industry data and forecasts relied upon by us; and
- the absence of adverse changes in relevant laws or regulations.

There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. See the “Risk Factors” section in our Annual Information Form for the year ended December 31, 2022 as well as our other public filings with the Canadian securities regulatory authorities and the United States Securities and Exchange Commission for further risk factors that might affect us and our business. Please also refer to the “Risks and Uncertainties” section, which can be found below. Should one or more of the risks, uncertainties or other factors outlined in our Annual Information Form for the year ended December 31, 2022 as well as our other public filings materialize, our objectives, strategies or intentions change, or any of the factors or assumptions underlying the forward-looking information prove incorrect, our actual results and our plans and targets could vary significantly from what we currently foresee. Accordingly, we warn investors to exercise caution when considering statements containing forward-looking information and that it would be unreasonable to rely on such statements as creating legal rights regarding our future results or plans or targets. All of the forward-looking information in this MD&A is qualified by the cautionary statements herein.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this MD&A, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this MD&A, to conform these statements to actual results or to changes in our expectations.

CORPORATE PROFILE

We are a clinical-stage biopharmaceutical company working to better the lives of patients suffering from persistent cough, starting with the development of camlipixant (BLU-5937) for the treatment of refractory chronic cough (“RCC”). Camlipixant, is a highly selective second-generation antagonist of the P2X3 receptor, a clinically validated target to treat cough hypersensitivity. We are currently developing camlipixant for the treatment of adults with RCC. We believe RCC, which includes a pathophysiology that is mediated through the P2X3 receptor, represents an area of significant unmet medical need and its treatment represents a potentially large market opportunity. We believe camlipixant’s characteristics observed in our preclinical studies, Phase 1 and Phase 2 clinical trials support the development of camlipixant and, if approved, position it as a potentially best-in-class agent in the P2X3 receptor antagonist class for the treatment of RCC. On December 13, 2021, we announced positive topline results from SOOTHE, a Phase 2b trial evaluating the tolerability and clinical activity of camlipixant in participants diagnosed with RCC. On July 12, 2022, we announced a positive End-of-Phase 2 (“EOP2”) meeting with the U.S. Food and Drug Administration (“FDA”) and the details of the CALM Phase 3 clinical program for camlipixant for the treatment of RCC. In addition, we have received scientific advice on the CALM program from the European Medicines Agency’s (“EMA”) Committee for Medicinal Products for Human Use (“CHMP”) and from the UK’s Medicines and Healthcare products Regulatory Agency (“MHRA”). In November 2022, we initiated the CALM Phase 3 clinical program, which is composed of two pivotal trials, CALM-1 and CALM-2, each evaluating the efficacy, safety and tolerability of camlipixant in RCC. Both trials are running concurrently, and each will recruit approximately 675 adult participants. We expect to report topline data from CALM-1 in the second half of 2024 and from CALM-2 in 2025. On April 5, 2023, we announced positive data from our Phase 1 bioavailability equivalence study evaluating a once-daily, ER formulation of camlipixant in comparison to the twice-daily (“BID”) Immediate Release (“IR”) formulation. We expect to continue the development of the ER formulation of camlipixant by conducting a multiple dose study, .

Our shares trade on the Nasdaq Global Market (“Nasdaq”) and on the Toronto Stock Exchange (“TSX”) both under the symbol “BLU”.

BUSINESS OVERVIEW

Key Updates

GSK plc (“GSK”) to acquire BELLUS Health.

- On April 18, 2023, GSK and BELLUS Health announced that they have entered into an agreement under which GSK will acquire BELLUS Health for US\$14.75 per share of common stock in cash representing an approximate total equity value of US\$2.0 billion. The per-share price represents a premium of approximately 103% to our closing stock price on April 17, 2023 and a premium of approximately 101% to our volume-weighted average price (“VWAP”) over the prior 30 trading days. The transaction remains subject to shareholder and regulatory approvals and is expected to close in the third quarter of 2023 or earlier.

Actively advancing the CALM Phase 3 clinical program (CALM-1 and CALM-2 trials) for camlipixant (BLU-5937) in RCC, with patient enrollment ongoing.

- We initiated the CALM Phase 3 clinical program in the fourth quarter of 2022, with patient enrollment ongoing. The CALM program consists of two pivotal trials, CALM-1 and CALM-2, with the primary endpoint of 24-hour cough frequency measured at 12- and 24-weeks, respectively, using the VitaloJAK cough monitoring system.
- We expect topline results from CALM-1 in the second half of 2024, and we expect topline results from CALM-2 in 2025.

Pursuing development of our P2X3 pipeline.

- We reported positive results from our Phase 1 clinical trial investigating the safety, tolerability, and pharmacokinetic profile of a once-daily, ER formulation of camlipixant. The ER formulation demonstrated equivalent bioavailability to the twice-daily IR formulation. In addition, the ER formulation was well tolerated, with safety data observed to be consistent with previous camlipixant trials and no taste-related adverse events reported.

Presenting at the upcoming American Thoracic Society (“ATS”) 2023 International Conference, being held in Washington, DC from May 19-24, 2023.

- We will be presenting an oral abstract entitled “Response in Patient-reported Cough Severity in SOOTHE, a Phase 2b Trial of Camlipixant in Refractory Chronic Cough” on Sunday, May 21, 2023 at 3:15-3:27 p.m. ET, and a poster presentation entitled “Model-based Dose Selection for Phase 3 Trials of the Selective P2X3 Antagonist Camlipixant in Refractory Chronic Cough” on Monday, May 22, 2023 at 11:30-1:15 p.m. ET.
- Additionally, conference participants are invited to attend two BELLUS Health-sponsored Guru Bars on Tuesday, May 23, 2023. Booth #1100 entitled “Refractory Chronic Cough: Is it All in Our Head?” will be available at 1:00-1:20 p.m. ET and Booth #1200 entitled “Understanding the Roadmap to Diagnosing Refractory Chronic Cough” will be available at 1:30-1:50 p.m. ET.

Presented at the American Academy of Allergy, Asthma & Immunology (“AAAAI”) Annual Meeting and at the American Society of Clinical Pharmacology & Therapeutics (“ASCPT”) 2023 Annual Meeting.

- We presented clinical data from the Phase 2b SOOTHE trial at the AAAAI Annual Meeting, held in San Antonio, Texas from February 24-27, 2023. We also presented results from phase 1 drug-drug interactions studies of camlipixant at the ASCPT 2023 Annual Meeting, held in Atlanta, Georgia from March 22-24, 2023.

Ended the first quarter of 2023 with cash, cash equivalents and short-term investments totaling \$313.0 million.

BUSINESS SECTION

Our Pipeline

We are developing camlipixant (BLU-5937), a potent, highly selective, small molecule antagonist of the P2X3 receptor, as an oral therapy to reduce cough frequency and improve quality of life in patients with RCC. We are also developing a QD formulation of camlipixant.

PROGRAM Indication / Project	DEVELOPMENT				STATUS	
	Preclinical	Phase 1	Phase 2	Phase 3	Worldwide Rights	Next Anticipated Step
Camlipixant						
Refractory Chronic Cough (BID Formulation)						2H 2024: CALM-1 Topline Results 2025: CALM-2 Topline Results
Pharmacokinetics (QD Formulation)						Conduct a multiple dose study of the ER formulation

Our lead indication currently pursued for camlipixant is RCC, defined as a cough lasting more than eight weeks that is unexplained or persists despite treatment of potential associated causes. It is estimated that approximately 26 million adults in the United States suffer from chronic cough of which approximately 9 million patients are identified as having RCC, based on company-sponsored market surveys. It is also estimated that approximately 9 million patients suffer from RCC in the United Kingdom, Germany, France, Spain and Italy. Additionally, RCC is highly prevalent in Asia. Many patients report that their condition has a marked effect on their quality of life including sleep disruption, fatigue, urinary incontinence, and disruption of social interactions. Currently, there is no pharmacological therapy approved specifically for the treatment of RCC outside of Japan and Switzerland. Available treatment options are limited and may have unsatisfactory benefits and/or significant safety and tolerability issues. We believe that camlipixant, if approved, may be adopted by physicians as an oral cough therapy in patients for whom cough hypersensitivity is a significant etiology of their cough.

In July 2020, we announced topline results from our Phase 2a RELIEF clinical trial of camlipixant that demonstrated proof-of-concept in RCC participants. Numerical differences in favor of camlipixant were observed in the primary endpoint of reduction in cough frequency. Clinically meaningful and statistically significant reductions in cough frequency were observed in two pre-specified sub-groups of participants with baseline awake cough frequency of ≥ 20 coughs/h (80% of trial participants) and ≥ 32 coughs/h (50% of trial participants). The treatment-emergent adverse events (“TEAEs”) profile was comparable to placebo with the exception of the known class effect of taste disturbance.

The Phase 2b trial SOOTHE trial was initiated at the end of 2020, with the first participant dosed in December 2020. In December 2021, we announced that the 50 mg and 200 mg BID doses of camlipixant in our SOOTHE trial for the treatment of RCC achieved statistical significance on the primary endpoint with 34% placebo-adjusted reduction in 24-hour cough frequency observed ($p \leq 0.005$) at day 28. Camlipixant was generally well-tolerated at all doses and the treatment-emergent adverse events (“TEAEs”) profile was comparable to placebo with the exception of the known class effect of taste disturbance. A dose response was observed between the 12.5 mg and 50 mg BID doses.

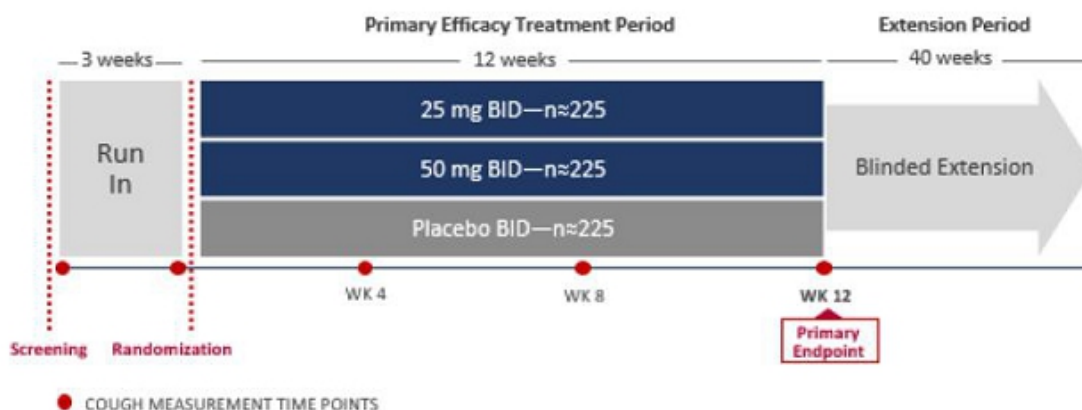
On July 12, 2022, we announced a positive EoP2 meeting with the FDA and the details of the CALM Phase 3 clinical program design for camlipixant. On November 14, 2022, we announced that, subsequent to our EoP2 meeting with the FDA, we had received scientific advice on the design of our CALM Phase 3 clinical program from both EMA and MHRA. We also disclosed that we had initiated our CALM Phase 3 program with patient screening ongoing, and topline results are expected in the second half of 2024 for CALM-1 and in 2025 for CALM-2. Additionally, we announced that we had conducted validation work on the VitaloJAK cough monitoring system comparing compressed vs. non-compressed recordings in a cohort of 45 SOOTHE Phase 2b trial participants. The results demonstrated a sensitivity of 98.7%, with no systematic error observed. We submitted a validation protocol and statistical analysis plan to the FDA in the fourth quarter of 2022.

On April 5, 2023 we announced that the Phase 1 bioavailability equivalence study evaluating a once-daily, ER formulation of camlipixant in comparison to the twice-daily, IR formulation was positive and that the ER formulation demonstrated equivalent bioavailability to the IR formulation. Additionally, the ER formulation was well tolerated, with safety data observed to be consistent with previous camlipixant trials and no taste-related adverse events reported. A patent application has been filed covering once-daily formulations of camlipixant. We expect to continue the development of the ER formulation of camlipixant by conducting a multiple dose study.

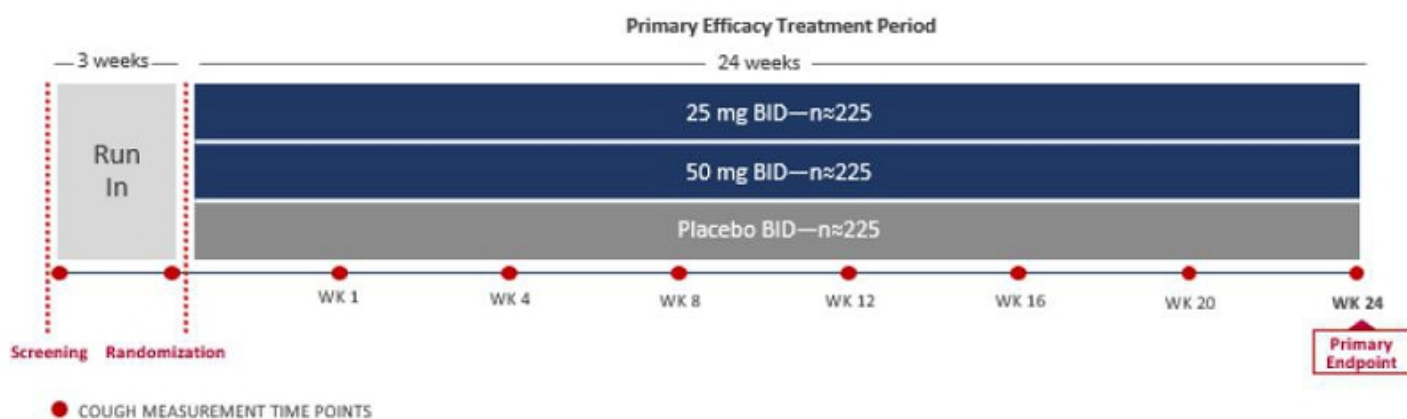
CALM Phase 3 Clinical Program

The ongoing CALM Phase 3 clinical program is composed of two pivotal trials, CALM-1 and CALM-2, each evaluating the efficacy, safety and tolerability of camlipixant in approximately 675 adults with RCC. CALM-1 and CALM-2 are placebo-controlled, parallel-arm trials randomized 1:1:1 with treatment arms of 25 mg BID, 50 mg BID and placebo. The primary endpoint of 24H cough frequency will be measured at 12-weeks for CALM-1 and 24-weeks for CALM-2 using the VitaloJAK cough monitoring system in a primary patient population enriched for baseline with 24H cough frequency of ≥ 20 coughs/hour (“coughs/h”). Secondary efficacy endpoints include a Visual Analogue Scale (“CS-VAS”), the Leicester Cough Questionnaire (“LCQ”), Chronic Cough Diary (“CCD”), and reduction in cough frequency in a broader population including the primary enriched population and an extended population with baseline 24H cough frequency < 20 coughs/h. CALM-1 will have a 40-week randomized extension period and an additional 24-week open label extension. CALM-2 will have a 28-week open label extension. Topline data from CALM-1 and CALM-2 are expected in the second half of 2024 and in 2025, respectively. Both trials are expected to include 285 global sites, with approximately 65% of the total in North America and Western Europe, and are currently enrolling patients. The design and analysis of our CALM Phase 3 clinical trials is subject to continuing feedback and interactions with the FDA and other regulatory authorities.

CALM-1



CALM-2



Phase 2b SOOTHE Clinical Trial

The SOOTHE trial was a multicenter, randomized, double-blind, four-week, parallel-arm, placebo-controlled Phase 2b trial evaluating the efficacy and tolerability of three doses of camlipixant (12.5 mg, 50 mg and 200 mg BID) in 310 participants with RCC. Two hundred and forty-nine (249) participants with a baseline awake cough frequency of ≥ 25 coughs per hour were randomized across four treatment arms (1:1:1:1) evaluating the three active doses and placebo in the main trial. Treatment arms were stratified to balance the number of participants per treatment group with baseline awake cough frequency ≥ 45 coughs per hour across trial arms. The primary efficacy endpoint was the placebo-adjusted change in the 24-hour cough frequency from baseline to day 28 collected with a cough recorder. An exploratory group of an additional 61 participants with a baseline awake cough frequency of ≥ 10 and < 25 coughs per hour were randomized across two arms (1:1) evaluating one active dose (200 mg BID) and placebo to further investigate the effect of camlipixant in participants with lower cough frequency. Phase 2b clinical trial enrolled participants at 116 sites, of which approximately 50% were in the United States. The SOOTHE trial was initiated in December 2020. On December 13, 2021, we announced the positive topline data from the SOOTHE trial. The primary efficacy endpoint was statistically significant with a 34% placebo-adjusted reduction in 24-hour cough frequency observed at 50 mg and 200 mg BID doses.

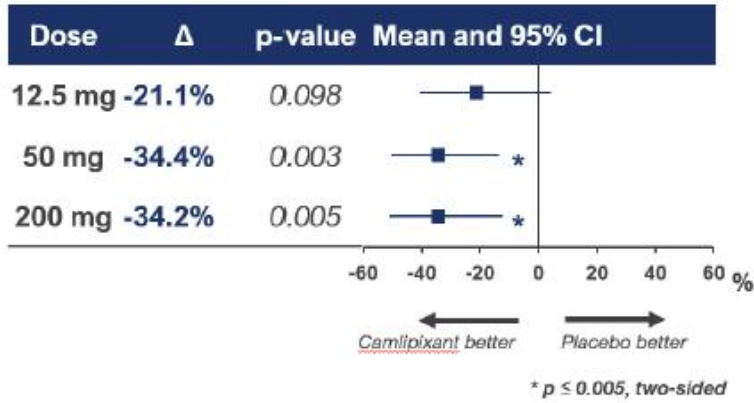
Efficacy Results:

The SOOTHE clinical trial, which enrolled 249 participants with a baseline awake cough frequency of ≥ 25 per hour, demonstrated a clinically meaningful and statistically significant placebo-adjusted reduction in 24-hour cough frequency of 34% at the 50 mg and 200 mg BID dose levels of camlipixant ($p \leq 0.005$) at day 28. The 12.5 mg BID dose demonstrated a statistical trend with 21% reduction in placebo-adjusted 24-hour cough frequency ($p = 0.098$) with a dose response observed between the 12.5 mg and 50 mg BID doses.

SOOTHE Primary Efficacy Endpoint

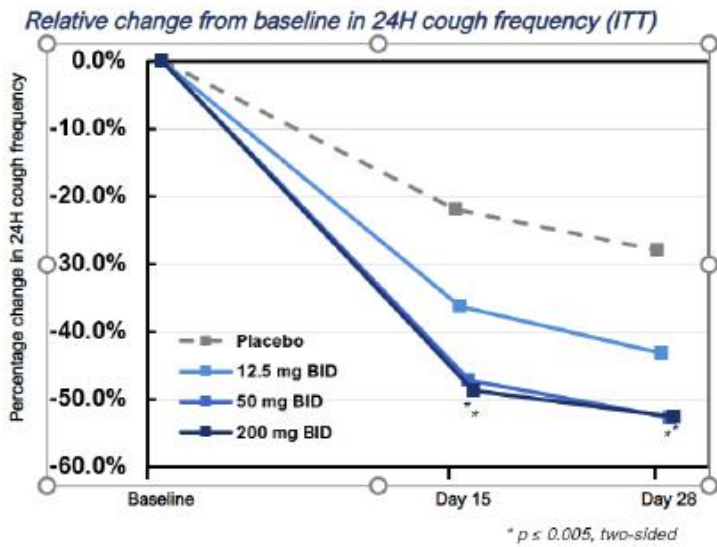
Placebo-adjusted 24H cough frequency change from baseline at Day 28¹

Intent-to-treat analysis



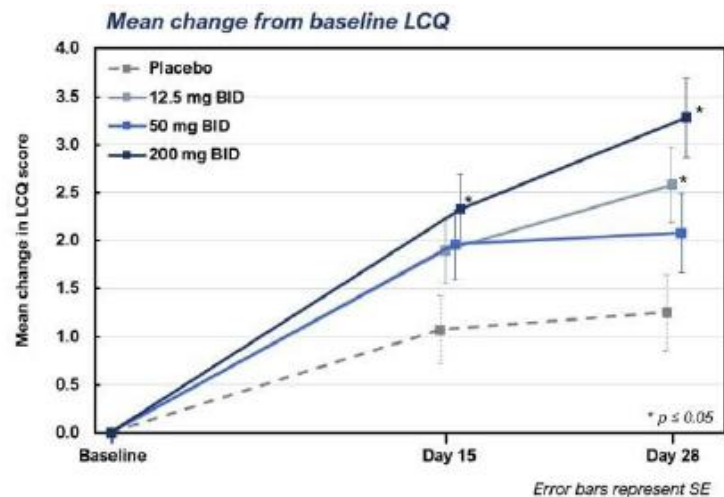
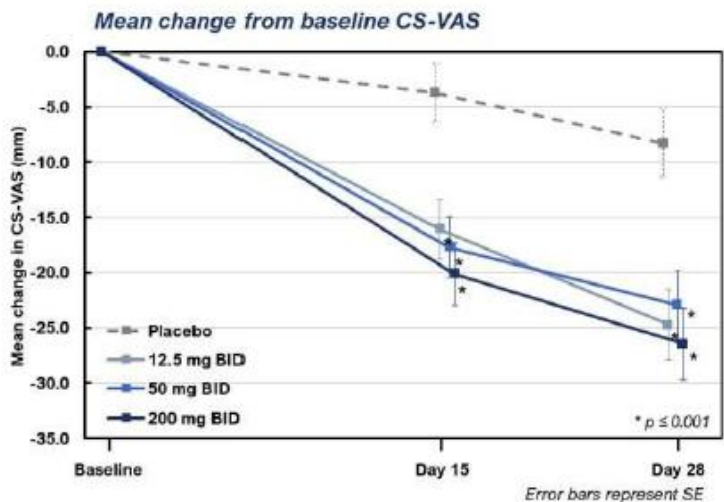
1. Geometric mean ratio of difference from baseline between camlipixant doses and placebo is estimated by back transformation of the LS mean difference. Percent treatment benefit over placebo in mean cough frequency is defined as $100 \times ((\text{geom. LS mean Ratio}) - 1)$.

The change from baseline in 24-hour cough frequency was 53% at day 28 with 50 mg and 200 mg BID doses.



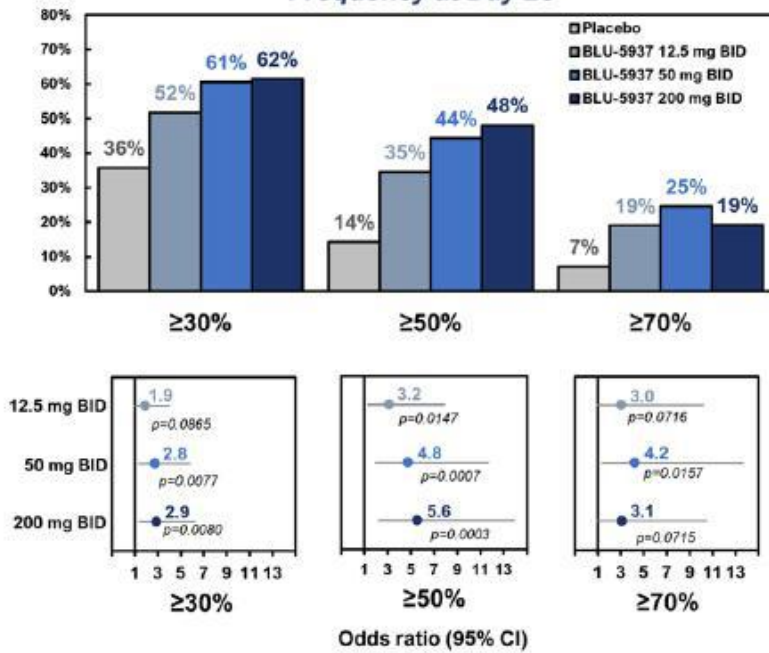
SOOTHE Secondary Endpoints: Change from Baseline in Key Patient-Reported Outcomes

Patient Reported Outcomes (“PROs”) constituted secondary endpoints and included CS-VAS and LCQ. Even though SOOTHE was not powered to demonstrate statistical significance on the PROs, a clinically meaningful and nominally significant benefit of camlipixant was observed at multiple timepoints in the PROs.



Responder analyses showed that, after 28 days of treatment, $\geq 60\%$ of participants achieved a clinically meaningful $\geq 30\%$ reduction in 24H cough frequency at the two higher doses, with $\geq 44\%$ and $\geq 19\%$ achieving responses of $\geq 50\%$ and $\geq 70\%$ reductions, respectively. Odds ratios numerically favored treatment over placebo for every dose of camlipixant. The 50 and 200 mg treatment groups demonstrated a nominally significant likelihood ($p < 0.01$) to achieve a clinically meaningful response ($\geq 30\%$) over placebo.

Responder rates in 24H Cough Frequency at Day 28



Safety and Tolerability Results:

Camlipixant's safety and tolerability data from SOOTHE were consistent with previous trials, including the Phase 2a RELIEF trial. Camlipixant was well-tolerated with low impact on taste perception. Taste-related side effects were reported in 4.8%, 6.5% and 4.8% of participants at 12.5 mg, 50 mg and 200 mg doses, respectively. No participant reported complete or partial taste loss and there were no discontinuations due to taste-related adverse events.

The TEAE profile was comparable to placebo except for the known class-related event of taste disturbance. There were no treatment emergent serious adverse events reported in the trial.

Treatment Emergent Adverse Events

n (%)	Placebo (n= 63)	Camlipixant 12.5 mg BID (n= 62)	Camlipixant 50 mg BID (n= 62)	Camlipixant 200 mg BID (n= 62)
Subjects with ≥1 TEAE	22 (34.9%)	23 (37.1%)	13 (21.0%)	19 (30.6%)
Subjects with ≥1 TESAE	0	0	0	0
Subjects with TEAE leading to discontinuation, n (%)[*]	1 (1.6%)	0	0	2 (3.2%)
Most Common TEAEs (≥5% at any dose)[†]				
Nausea	0	0	5 (8.1%)	2 (3.2%)
Dysgeusia	0	3 (4.8%)	4 (6.5%)	3 (4.8%)
UTI	0	3 (4.8%)	0	0

[†] No TEAE reported with an incidence ≥5% in the exploratory population

^{*} Placebo: worsening of cough; camlipixant 200 mg BID: worsening of cough, dry mouth

Incidence of Taste Disturbance Adverse Events

	Placebo (n= 63)	Camlipixant 12.5 mg BID (n= 62)	Camlipixant 50 mg BID (n= 62)	Camlipixant 200 mg BID (n= 62)
Taste alteration (dysgeusia)	0	3 (4.8%)	4 (6.5%)	3 (4.8%)
Partial taste loss (hypogeusia)	0	0	0	0
Complete taste loss (ageusia)	0	0	0	0
Total taste disturbances	0	3 (4.8%)	4 (6.5%)	3 (4.8%)

Phase 2a RELIEF Clinical Trial

The Phase 2a RELIEF clinical trial, for which we announced topline results in July 2020, established proof-of-concept for camlipixant (BLU-5937) in the treatment of RCC participants. Numerical differences in favor of camlipixant were observed in the primary endpoint of reduction in cough frequency. The RELIEF trial did not achieve statistical significance for the primary endpoint of reduction in placebo-adjusted cough frequency at any dose tested in the intent to treat population (n=67); however, pre-specified analysis showed a statistically significant interaction between baseline cough frequency and treatment effect, and prespecified subgroup analyses in participants with baseline awake cough frequency of ≥ 20 coughs/h and ≥ 32 coughs/h (median), revealed statistically significant and clinically meaningful reductions in cough frequency relative to placebo:

- A statistically significant interaction (p=0.0258) was observed between average awake cough frequency at baseline and treatment effect, linking higher baseline cough frequency with improved treatment benefit.
- Participants with awake cough frequencies ≥ 20 coughs/h (representing 80% of total trial participants) at baseline saw placebo-adjusted reductions in awake cough frequency of 20% (p=0.001), 18% (p=0.02), 19% (p=0.03) and 27% (p=0.003) at doses of 25 mg, 50 mg, 100 mg and 200 mg BID, respectively.
- Participants with awake cough frequencies at or above the baseline median of 32 coughs/h at baseline (representing 50% of total trial participants) saw placebo-adjusted reductions in awake cough frequency of 28%, 28%, 30% and 32% (all p < 0.0015) at doses of 25 mg, 50 mg, 100 mg and 200 mg BID, respectively.

Camlipixant was generally well-tolerated and showed an adverse event profile comparable to placebo except for an increased incidence of the known class-related adverse event of taste disturbance.

Taste disturbance adverse events were reported in 10% or less of the participants. Additionally, no complete loss of taste was observed at any dose, no severe taste adverse event was reported and no dropouts due to taste disturbance occurred.

RELIEF enrolled participants in 16 sites (8 in the United Kingdom and 8 in the United States) and randomized a total of 68 RCC participants; 67 were included in the intent to treat population. 52 participants completed both treatment periods and 16 participants dropped out in total, including 13 as a result of difficulties with conducting follow-up visits due to the COVID-19 pandemic or early termination of the trial. There were three additional non-drug related discontinuations.

Learnings from Phase 2a RELIEF Data

Based on the RELIEF trial results, we believe cough frequency at baseline is a key indicator of potential treatment benefit, with subgroup analysis of participants having baseline awake cough frequencies ≥ 20 coughs/h and ≥ 32 coughs/h demonstrating statistically significant and clinically meaningful benefit at all doses. Based on these analyses and the patient level data of participants with baseline awake cough frequency of ≥ 20 coughs/h and < 32 coughs/h, we selected a minimum baseline awake cough frequency of 25 coughs/h as an inclusion criterion for the Phase 2b trial.

No dose response was observed in the Phase 2a RELIEF trial. Plasma concentrations achieved in RELIEF were also consistent with achieving receptor occupancies in the 75-95+% range. Based on this information, doses of 12.5 mg BID, 50 mg BID and 200 mg BID were selected for the Phase 2b SOOTHE trial.

Development of a QD Formulation

Camlipixant (BLU-5937) has exhibited favorable physicochemical and pharmacokinetic characteristics, including high solubility and permeability, good oral bioavailability, linear pharmacokinetic profile, and a low predicted therapeutic dose. On April 5, 2023 we announced that the Phase 1 bioavailability equivalence study evaluating a once-daily, ER formulation of camlipixant in comparison to the twice-daily, IR formulation demonstrated equivalent bioavailability to the IR formulation. Additionally, the ER formulation was well tolerated, with safety data observed to be consistent with previous camlipixant trials and no taste-related adverse events reported. A patent application has been filed covering once-daily formulations of camlipixant. We expect to continue the development of the ER formulation of camlipixant by conducting a multiple dose study.

Competitive Landscape

In addition to BELLUS Health, other companies are developing P2X3 receptor antagonist product candidates for the treatment of RCC, including Merck & Co. (“Merck”) and Shionogi & Co., Ltd (“Shionogi”). The positive Phase 2b SOOTHE results position camlipixant (BLU-5937) as a potential best-in-class product candidate in the P2X3 receptor class in terms of its clinical activity and tolerability profile, if confirmed in Phase 3 development and approved. Additionally, the greater selectivity for P2X3 receptor over P2X2/3 receptor observed for our product candidate, camlipixant, may contribute to supporting a favorable clinical and commercial profile.

The table below shows the selectivity, stage of development and dosing regimen of the different P2X3 receptor product candidates currently in development 1:

	1 ST IN CLASS P2X3 ANTAGONIST	2 ND GENERATION P2X3 ANTAGONISTS	
Company	 MERCK	 SHIONOGI	 Bellus HEALTH
Candidate	<u>Gefapixant</u>	<u>Sivopixant</u>	Camlipixant (BLU-5937)
Stage of Development	Approved in Japan, Switzerland EU/US Under Review	Phase 2b	Phase 3
Expected Next Steps	Submit additional information in U.S./EU in 1H 2023*	Evaluating Next Steps**	CALM-1 topline results expected in 2H 2024
Dosing	BID	QD	BID / QD in development
P2X3 vs. P2X2/3 Selectivity	3-7x ²	~ 250x ³	~ 1500x

*Merck 10K, Feb 23, 2023. Merck's NDA for gefapixant received a CRL by U.S. FDA in February 2022;

**Shionogi R&D Day, October 2022

1. Limited head to head studies have been conducted; data presented is derived from company specific disclosures.

2. Ford et al. (2013) FAS EB J. 27: 887.5-887.5

3. Kai et al. 2020 Abstract presented at: ACS Fall 2020 Virtual & Meeting Exposition; August 17-20, 2020

Merck announced in March of 2020 that the 45 mg BID dose MK-7264 (gefapixant) had reached statistical significance on the primary efficacy endpoint in both the Phase 3 trials, COUGH-1 and COUGH-2 and that the 15 mg BID dose had not achieved statistical significance in either trial. Pursuant to this announcement, in September 2020 at the European Respiratory Society (“ERS”) International conference, Merck presented these results in further detail. The 45 mg BID dose of gefapixant achieved a statistically significant result on its primary endpoint of placebo-adjusted reduction in 24-hour cough frequency (18% in the 12-week COUGH-1 trial and 16% in the 24-week COUGH-2 trial) but showed significant rates of taste disturbance adverse events (58% and 69% in the COUGH-1 and COUGH-2, respectively). In March 2021, Merck announced that the FDA had accepted gefapixant NDA for review. In January 2022, Merck announced that the Japan Ministry of Health, Labor and Welfare granted regulatory approval for gefapixant 45 mg tablets for the treatment of adults with RCC. Additionally, Merck reported that the FDA issued a Complete Response Letter (“CRL”), which included the need for additional analyses associated with “measurement of efficacy”. Merck further clarified in February 2022 that the CRL was not related to the safety of gefapixant, but to an algorithm and underlying methodology used by the audio recording device to assess efficacy. In May 2022, gefapixant was approved in Switzerland. In August 2022, Merck announced that it is performing additional analyses and anticipates submitting this information to the FDA in the first half of 2023 in response to the CRL. Merck also reported that the review period in the EU had been extended pending the receipt of additional information and it plans to submit the information to the EMA in the first half of 2023. Outside of Japan and Switzerland, gefapixant remains an investigational treatment under review by regulatory authorities, such as the EMA.

Shionogi announced topline results of its Phase 2a clinical trial of S-600918 (sivopixant) in participants with RCC at the ERS International Congress in October 2019, which included a placebo-adjusted reduction in 24-hour cough frequency of 32% ($p=0.055$) and a rate of 6.5% of taste disturbance adverse events. The mean cough per hour frequency at baseline was 56. At the 2020 ERS International Congress, Shionogi reported that it observed an interaction between baseline cough frequency and treatment effect in its Phase 2a clinical trial; this prompted the utilization of a minimal cough frequency threshold as an inclusion criterion in the Phase 2b clinical trial of sivopixant. On September 29, 2021, Shionogi announced that the primary endpoint of placebo adjusted change in 24-hour cough frequency in its Phase 2b clinical trial of sivopixant was not met at any dose in the full analysis set (+13%, -2% and -12% for 50 mg, 150 mg and 300 mg QD, respectively). Post-hoc analysis of participants with a 24-hour cough frequency ≥ 10 or more coughs/h at baseline demonstrated 23% reduction in placebo-adjusted cough frequency for 300 mg QD. Taste related adverse events reported for the 50 mg, 150 mg, 300 mg and placebo groups in the safety analysis population were 2%, 14% and 33% and 2.9%, respectively. In December 2022, the results from the Phase 2b clinical trial of sivopixant were published in *Lung*. Shionogi indicated then that it was planning to discuss dose selection and Phase 3 clinical trial design at an upcoming EOP-2 meeting with the FDA. In a conference call in January 2022, Shionogi mentioned in its presentation that it was preparing for a Phase 3 clinical trial. On October 12, 2022, Shionogi mentioned in a presentation that “competitor landscape and regulators’ comments on endpoint” will determine whether to conduct Phase 3.

Market Opportunity in Chronic Cough

According to the 2019 National Ambulatory Medical Care Survey, across the U.S. in 2019, cough was the reason for 15 million in-office physician consultations and 4.7 million emergency visits.

We estimate that up to 10% of the adult population in developed countries suffer from chronic cough, including the United States, nations in the European Union and the United Kingdom. This represents approximately 26 million patients with chronic cough in the United States alone.

We estimate that approximately 30% of chronic cough patients, or approximately 9 million patients in the U.S., are uncontrolled or have RCC, which is the expected addressable patient population for camlipixant. It is also estimated that approximately 9 million patients suffer from RCC in the EU5 countries. Additionally, RCC is prevalent in Asia. RCC patients continue to cough despite treatment for potential underlying causes of their cough or have a cough that is unexplained. We estimate that approximately one-third, or approximately 3 million, of these RCC patients in the U.S. have been coughing for over a year, a key inclusion criteria in current RCC clinical trials, including our Phase 2a RELIEF clinical trial and Phase 2b SOOTHE clinical trial of camlipixant. Many patients report that their condition has a marked effect on their quality of life including sleep disruption, fatigue, urinary incontinence, and disruption of social interactions. Currently, there is no pharmacological therapy approved specifically for the treatment of RCC outside of Japan and Switzerland. Available treatment options outside of Japan and Switzerland are limited and may have inadequate benefit and/or significant safety and tolerability issues. We believe that camlipixant, if approved, may be adopted by physicians as an oral cough therapy in patients for whom cough-hypersensitivity is the primary etiology.

In October 2022, we completed large quantitative surveys of 1,483 U.S. pulmonologists, allergists, ENTs, gastroenterologists, and primary care physicians showing that there are about 8.6 million RCC patients in the United States and 1.8 million RCC patients are currently being seen by specialists.

Supporting Preclinical and Clinical Development Activities

Non-clinical toxicology studies and clinical pharmacology studies to support an anticipated NDA filing and inform labeling for RCC are ongoing or planned.

Chemistry, Manufacturing, and Controls (“CMC”)

We have a primary supply chain in place with the capacity to produce the required clinical supplies to support a Phase 3 clinical program in RCC and commercial supplies for a potential launch, if camlipixant is approved. We continue to work on activities associated with manufacturing process optimization and upscaling to support a potential commercial launch.

BLU-5937 in Other P2X3 Hypersensitization-Related Disorders

We believe the results of our Phase 2b SOOTHE clinical trial further validate the role of P2X3 receptor in cough hypersensitivity. We intend to evaluate potential opportunities to study camlipixant in additional cough indications where hypersensitivity plays an important role.

In addition to RCC, the mechanism of action of camlipixant may also have broad therapeutic applicability across other neuronal cough hypersensitivity indications. The Company is evaluating potential opportunities to study camlipixant in additional cough indications where cough hypersensitivity plays an important role.

Intellectual Property

Our camlipixant program is protected by a comprehensive patent estate comprised of issued and allowed patents, as well as pending patent applications. We have secured composition of matter patent protection for camlipixant in all major pharmaceutical markets, including the United States of America, Europe, Japan and China, all with an expiration date of 2034. Under certain circumstances, such patent term may be extended for up to five years in certain jurisdictions such as the United States, Europe and Japan. In addition, we have secured method of use patent protection in the United States for avoiding loss of taste response while treating a chronic cough patient with camlipixant, expiring in 2038, and have received intention to grant notifications from the European Patent Office and the Japanese Patent Office. Patent applications with similarly broad claims are currently pending in other industrialized nations. A patent application has been filed covering once-daily formulations of camlipixant. We own 100% of the intellectual property estate covering camlipixant and its use for the treatment of chronic cough.

BELLUS Health acquisition by GSK

On April 18, 2023, GSK and BELLUS Health announced that they have entered into an agreement under which GSK will acquire BELLUS Health for \$14.75 per share of common stock in cash representing an approximate total equity value of \$2.0 billion.

Under the terms of the agreement, the acquisition will be effected through a Plan of Arrangement pursuant to the Canada Business Corporations Act. Subject to customary conditions, including court approval, the approval of the acquisition by at least 66.67% of the votes cast at a meeting of BELLUS Health's shareholders and a majority of the votes cast by non-interested shareholders at such meeting, and approval by the appropriate regulatory agencies, the transaction is expected to close in the third quarter of 2023 or earlier.

The per-share price represents a premium of approximately 103% to BELLUS Health's closing stock price on 17 April 2023 and a premium of approximately 101% to BELLUS Health's volume-weighted average price (VWAP) over the last 30 trading days. Our Board of Directors has unanimously recommended that BELLUS Health's shareholders vote in favour of the approval of the acquisition at the special meeting of shareholders to be held on June 16, 2023.

There can be no assurances that the acquisition will be completed, or that it will be completed on the expected timeline. If the acquisition is not approved by shareholders or if it is not completed for any other reason, shareholders will not receive any payment for any of their shares in connection with the acquisition, and the arrangement agreement with GSK may be terminated. If this occurs, BELLUS Health will continue to carry on as a reporting issuer in the normal and usual course, and will continue to face the risks and limitations that it currently faces with respect to its affairs, business and operations and future prospects. Note that the failure to complete the acquisition could negatively impact the share price and the Company, and that BELLUS Health may be required, in certain circumstances, to pay a termination fee of \$75 million. If the acquisition is not approved by shareholders, the Company will pay expense reimbursement for reasonable, documented out-of-pocket third party transaction expenses incurred by GSK in connection with the acquisition, in an amount not to exceed \$10 million.

RESULTS OF OPERATIONS

For the three-month period ended March 31, 2023, net loss amounted to \$25,060,000 (\$0.20 per share), compared to \$14,352,000 (\$0.13 per share) for the corresponding period the previous year. The increase in net loss is primarily attributable to higher research and development expenses in relation to the development of camlipixant (BLU-5937), with the initiation of our CALM Phase 3 clinical program in the fourth quarter of 2022.

Research and development expenses, net of research tax credits, amounted to \$22,335,000 for the three-month period ended March 31, 2023, compared to \$11,254,000 for the corresponding period the previous year, an increase of \$11.0 million or 98% year over year. The increase is primarily attributable to higher external R&D expenses incurred for the development of camlipixant, mainly for activities in relation to our CALM Phase 3 clinical program, which was initiated in the fourth quarter of 2022. The increase is also due to higher stock-based compensation expense of \$670,000 in relation to our stock option plan and higher workforce expenses due to an increase in headcount to support the development of camlipixant.

General and administrative expenses amounted to \$5,392,000 for the three-month period ended March 31, 2023, compared to \$4,050,000 for the corresponding period the previous year, an increase of \$1.3 million or 33% year over year. The increase is mainly attributable to higher external G&A expenses, as well as to higher stock-based compensation expense of \$229,000 in relation to our stock option plan.

Net finance income amounted to \$2,683,000 for the three-month period ended March 31, 2023, compared to \$973,000 for the corresponding period the previous year. The increase in net finance income is mainly attributable to higher interest income of \$2,834,000 due to the increased cash, cash equivalents and short-term investments position following the July 2022 Offering and the increase in interest rates, offset in part by lower foreign exchange gain of \$868,000 in the current period resulting from the conversion in U.S. dollars of our net monetary assets denominated in Canadian dollars.

Quarterly Results (Unaudited)*(in thousands of dollars, except per share data)***Quarterly Results***(in thousands of dollars,*

	2023 Q1	2022 Q4	2022 Q3	2022 Q2	2022 Q1	2021 Q4	2021 Q3	2021 Q2
Revenues	\$ 3	\$ 4	\$ 4	\$ 4	\$ 4	\$ 4	\$ 4	\$ 4
Expenses:								
Research and development, net	22,335	17,448	17,241	12,460	11,254	12,334	19,054	15,201
General and administrative	5,392	4,229	5,838	5,379	4,050	4,167	3,821	2,805
Total operating expenses	27,727	21,677	23,079	17,839	15,304	16,501	22,875	18,006
Operating loss	(27,724)	(21,673)	(23,075)	(17,835)	(15,300)	(16,497)	(22,871)	(18,002)
Net finance income (costs)	2,683	3,446	(1,656)	(900)	973	1,534	(10)	174
Loss before income taxes	(25,041)	(18,227)	(24,731)	(18,735)	(14,327)	(14,963)	(22,881)	(17,828)
Income taxes (recovery)	19	19	(25)	41	25	(199)	-	-
Net loss	\$ (25,060)	\$ (18,246)	\$ (24,706)	\$ (18,776)	\$ (14,352)	\$ (14,764)	\$ (22,881)	\$ (17,828)

The variation of the net loss of a quarter compared to the corresponding quarter of the previous year are explained by the elements in the following paragraph.

The increase in net loss for the first quarter of 2023 and fourth quarter of 2022 is primarily attributable to an increase in research and development expenses. The increase in net loss for the third quarter of 2022 is primarily attributable to an increase in foreign exchange loss resulting from the conversion in US dollars of our net monetary assets denominated in Canadian dollars. The increase in net loss for the second quarter of 2022 is primarily attributable to higher general and administrative expenses.

Related Party Transactions

Dr. Francesco Bellini is the Chairman of our Board of Directors and provides ongoing advisory services under the terms of a consulting and services agreement between us and Picchio International Inc. ("Picchio International"), wholly-owned by Dr. Francesco Bellini and his spouse. Picchio International receives a monthly fee of CAD\$20,833, plus the reimbursement of applicable expenses for services rendered under the agreement. The agreement has a one-year term renewable for successive one-year terms. We have recorded fees and expenses of \$71,000 and \$75,000 (each equivalent to CAD\$95,000) under the consulting and services agreement for the three-month periods ended March 31, 2023 and 2022, respectively.

FINANCIAL CONDITION

Liquidity and Capital Resources

As at March 31, 2023, we had available cash, cash equivalents and short-term investments totaling \$312,989,000, compared to \$337,057,000 as at December 31, 2022. For the three-month period ended March 31, 2023, the net decrease in cash, cash equivalents and short-term investments amounted to \$24,068,000, compared to \$14,838,000 for the corresponding period of the previous year. The net decrease for the three-month period ended March 31, 2023 is primarily attributable to funds used to finance our operating activities, mainly the research and development activities associated with our product candidate camlipixant.

Based on management's estimate and current level of operations, we believe that our current cash, cash equivalents and short-term investments, will be sufficient to extend our runway to the second half of 2025 and through expected topline results of both CALM-1 and CALM-2 trials. We may need to raise additional capital to fund our operations, develop camlipixant and prepare for commercialization.

In July 2022, we raised total gross proceeds of \$175,950,000 from the 2022 Offering by issuing a total of 19,021,622 common shares at a price of \$9.25 per share including the exercise of the underwriters' option to purchase 2,481,081 common shares. Net proceeds from the 2022 Offering amounted to approximately \$164,516,000. We intend to use the net proceeds from the 2022 Offering primarily to fund camlipixant (BLU-5937) research and development activities, working capital needs and other general corporate purposes.

In December 2021, we raised total gross proceeds of \$224,000,000 from the 2021 Offering by issuing a total of 28,000,000 common shares at a price of \$8 per share including the partial exercise of the underwriters' option to purchase 3,000,000 common shares. Net proceeds from the 2021 Offering amounted to \$209,729,000. We intend to use the net proceeds of the 2021 Offering primarily to fund research and development activities, general and administrative expenses, working capital needs and other general corporate purposes.

The use of proceeds presented in our prospectus supplements dated December 14, 2021 ("2021 Prospectus Supplement") and July 13, 2022 ("2022 Prospectus Supplement") did not include funds from the exercise of the underwriters' option to purchase additional common shares. Taking into consideration these additional funds, we intend to use the net proceeds of the 2021 Offering and 2022 Offering for the purposes and in the amounts indicated below.

	As per 2021 and 2022 Prospectus Supplements without options to purchase additional common shares	As at May 12, 2023, including options to purchase additional common shares
Camlipixant (BLU-5937) clinical trials in chronic cough	\$ 217.9 million	\$ 238.4 million
Manufacturing, formulation and scale-up	\$ 42.1 million	\$ 51.8 million
Other camlipixant project costs	\$ 36.5 million	\$ 42.4 million
Working capital and other general administration costs	\$ 34.4 million	\$ 41.5 million

As at March 31, 2023, we have used \$61.2 million of the 2021 and 2022 Offering net proceeds. For additional details regarding the development of campilixant, see “Business Section” – “Our Pipeline” in this MD&A.

On November 14, 2022, we entered into another ATM Sales Agreement (the “2022 ATM Sales Agreement”) with Jefferies pursuant to which we may from time to time sell through ATM distributions with Jefferies acting as sales agent (the “Agent”), our common shares for aggregate gross proceeds of up to \$80 million, including sales made directly on Nasdaq or on any other existing trading market for the common shares in the United States. No common shares will be offered or sold in Canada. The common shares would be issued at market prices prevailing at the time of the sale and, as a result, prices may vary between purchasers and during the period of distribution. We have no obligation to sell any of the common shares and may at any time suspend sales under the 2022 ATM Sales Agreement. We and the Agent may terminate the 2022 ATM Sales Agreement in accordance with its terms. During the three-month period ended March 31, 2023, no common shares were sold under the ATM program.

During the three-month period ended March 31, 2023, we purchased short-term investments with initial maturities greater than three months and less than a year for an aggregate amount of \$30,765,000, and redeemed at maturity or sold short-term investments for an aggregate amount of \$54,566,000 (purchased for \$22,500,000 and redeemed at maturity or sold for \$35,072,000 in the corresponding period of 2022).

There has been no significant change to our contractual obligations since December 31, 2022 other than in the ordinary course of business. As at March 31, 2023, we had commitments for expenditures related to contracts with service providers for research and development activities of approximately \$181,295,000 (approximately \$184,744,000 as at December 31, 2021), of which \$51,816,000 is expected to be payable in 2023, \$60,724,000 in 2024, \$51,456,000 in 2025 and \$17,299,000 in 2026.

On July 6, 2022, a Company stockholder, Jason Gallanti (the “Canadian Plaintiff”), filed a statement of claim before the Ontario Superior Court of Justice against the Company alleging negligent misrepresentation and claims under the Ontario Securities Act (“OSA”) and equivalent provincial securities legislation relating to disclosures concerning the Company’s Phase 2a RELIEF trial. The Canadian Plaintiff seeks certification of the action as a class proceeding on behalf of those who purchased the Company’s stock on the TSX, leave to pursue statutory claims under the OSA, compensatory damages, prejudgment and post-judgment interest, and costs of the action. Following the dismissal of the Plaintiff’s claim on September 22, 2022, the Canadian Plaintiff filed, on January 27, 2023, a motion to discontinue his claim and the parties are awaiting for the order approving the discontinuance to be entered and issued.

No provision has been made in the financial statements for the resolution of the above matter. Resolution of litigation could have an effect on our financial statements in the period that a determination is made, however, in management’s opinion, this litigation matter is not currently projected to have a material adverse effect on our financial position.

During the three-month period ended March 31, 2023, we granted 2,133,875 stock options, 168,556 stock options were exercised and 26,000 stock options were forfeited.

As at May 12, 2023, we had 126,798,993 common shares outstanding and 138,628,197 common shares on a fully diluted basis, including 11,829,204 stock options granted under the stock option plan.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of our condensed consolidated interim financial statements in accordance with IFRS requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. The reported amounts and note disclosures reflect management's best estimate of the most probable set of economic conditions and planned course of action. Actual results may differ from these estimates.

In preparing these condensed consolidated interim financial statements, the significant judgements made by management in applying our accounting policies and key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31, 2022.

Refer to the audited consolidated financial statements for the year ended December 31, 2022 for discussions on our accounting policies and estimates that are most important in assessing, understanding and evaluating our consolidated financial statements. Change in these estimates and assumptions could have a significant impact on our consolidated financial statements.

CHANGES IN ACCOUNTING POLICIES

The accounting policies and basis of measurement applied in our condensed consolidated interim financial statements as at March 31, 2023 are the same as those applied in our consolidated financial statements for the year ended December 31, 2022.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING (ICFR)

There have been no changes in our ICFR that occurred during the period beginning January 1, 2023 and ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our ICFR.

RISKS AND UNCERTAINTIES

We are a clinical-stage biopharmaceutical company that operates in an industry that is dependent on a number of factors that include the capacity to raise additional capital on reasonable terms, obtain positive results of clinical trials, obtain positive results of clinical trials without serious adverse or inappropriate side effects, and obtain market acceptance of its product. An investment in our common shares is subject to a number of risks and uncertainties. An investor should carefully consider the risks described in our AIF and our annual report on Form 40-F filed with the U.S. Securities and Exchange Commission, as well as our other public filings with the securities regulators before investing in our common shares. If any of such described risks occur, or if others occur, our business, operating results and financial condition could be seriously harmed, and investors may lose a significant proportion of their investment. There are important risks which management believes could impact our business. For information on risks and uncertainties, please refer to the "Risk Factors" section of our most recent AIF filed on SEDAR at www.sedar.com and included in the annual report on exhibit 99.3 to Form 40-F filed on EDGAR at www.sec.gov/edgar and our other public filings.

FORM 52-109F2
CERTIFICATION OF INTERIM FILINGS
FULL CERTIFICATE

I, Roberto Bellini, President and Chief Executive Officer of BELLUS Health Inc., certify the following:

1. **Review:** I have reviewed the interim financial report and interim MD&A (together, the “interim filings”) of BELLUS Health Inc. (the “issuer”) for the interim period ended March 31, 2023.
2. **No misrepresentations:** Based on my knowledge, having exercised reasonable diligence, the interim filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, with respect to the period covered by the interim filings.
3. **Fair presentation:** Based on my knowledge, having exercised reasonable diligence, the interim financial report together with the other financial information included in the interim filings fairly present in all material respects the financial condition, financial performance and cash flows of the issuer, as of the date of and for the periods presented in the interim filings.
4. **Responsibility:** The issuer’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as those terms are defined in Regulation 52-109 respecting Certification of Disclosure in Issuers’ Annual and Interim Filings (c. V-1.1, r. 27), for the issuer.
5. **Design:** Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer’s other certifying officer(s) and I have, as at the end of the period covered by the interim filings
 - (a) designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that
 - (i) material information relating to the issuer is made known to us by others, particularly during the period in which the interim filings are being prepared; and
 - (ii) information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
 - (b) designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer’s GAAP.
- 5.1 **Control framework:** The control framework the issuer’s other certifying officer(s) and I used to design the issuer’s ICFR is based on the framework established in the Internal Control – Integrated Framework by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).
- 5.2 **ICFR – material weakness relating to design:** N/A
- 5.3 **Limitation on scope of design:** N/A
6. **Reporting changes in ICFR:** The issuer has disclosed in its interim MD&A any change in the issuer’s ICFR that occurred during the period beginning on January 1, 2023 and ended on March 31, 2023 that has materially affected, or is reasonably likely to materially affect, the issuer’s ICFR.

Date: May 11, 2023.

/s/ Roberto Bellini

Roberto Bellini

President and Chief Executive Officer

FORM 52-109F2
CERTIFICATION OF INTERIM FILINGS
FULL CERTIFICATE

I, Ramzi Benamar, Chief Financial Officer of BELLUS Health Inc., certify the following:

1. **Review:** I have reviewed the interim financial report and interim MD&A (together, the “interim filings”) of BELLUS Health Inc. (the “issuer”) for the interim period ended March 31, 2023.
2. **No misrepresentations:** Based on my knowledge, having exercised reasonable diligence, the interim filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, with respect to the period covered by the interim filings.
3. **Fair presentation:** Based on my knowledge, having exercised reasonable diligence, the interim financial report together with the other financial information included in the interim filings fairly present in all material respects the financial condition, financial performance and cash flows of the issuer, as of the date of and for the periods presented in the interim filings.
4. **Responsibility:** The issuer’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as those terms are defined in Regulation 52-109 respecting Certification of Disclosure in Issuers’ Annual and Interim Filings (c. V-1.1, r. 27), for the issuer.
5. **Design:** Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer’s other certifying officer(s) and I have, as at the end of the period covered by the interim filings
 - (a) designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that
 - (i) material information relating to the issuer is made known to us by others, particularly during the period in which the interim filings are being prepared; and
 - (ii) information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
 - (b) designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer’s GAAP.
- 5.1 **Control framework:** The control framework the issuer’s other certifying officer(s) and I used to design the issuer’s ICFR is based on the framework established in the Internal Control – Integrated Framework by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).
- 5.2 **ICFR – material weakness relating to design:** N/A
- 5.3 **Limitation on scope of design:** N/A
6. **Reporting changes in ICFR:** The issuer has disclosed in its interim MD&A any change in the issuer’s ICFR that occurred during the period beginning on January 1, 2023 and ended on March 31, 2023 that has materially affected, or is reasonably likely to materially affect, the issuer’s ICFR.

Date: May 11, 2023.

/s/ Ramzi Benamar

Ramzi Benamar
Chief Financial Officer
