UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) March 9, 2023

BioXcel Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38410**	**82-1386754**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

555 Long Wharf Drive
New Haven, CT 06511
(Address of principal executive offices, including Zip Code)

(475) 238-6837
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001	BTAI	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition.

On March 9, 2023, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the three months and year ended December 31, 2022 and other matters described in the press release. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated March 9, 2023.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document

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 hereunto duly authorized.

Date: March 9, 2023

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart
Title: Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Operational Highlights

IGALMI™ (dexmedetomidine) commercial execution fully underway in 2023 with key focus on market access and demand generation through expanded field team

Multiple pivotal data readouts for BXCL501 expected in Q2 2023 in disease areas with 139 million agitation episodes,[1-3] including Alzheimer's-related agitation*

Positive data for BXCL701 in small cell neuroendocrine metastatic castration-resistant prostate cancer (SCNC) further validates Company's AI drug discovery and development expertise; Company exploring strategic options for OnkosXcel subsidiary

Company to host conference call at 8:30 a.m. ET today

NEW HAVEN, Conn., March 9, 2023 -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced its financial results for the fourth quarter and full year ended Dec. 31, 2022 and provided an update on key strategic initiatives.

"Last year was a transformational period for the Company, highlighted by the launch of our first AI-discovered commercial product, IGALMI, in under four years since initiating human trials. A new treatment option is now available for patients suffering from agitation associated with schizophrenia or bipolar I or II disorder," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "We are building on these achievements in 2023 and look to accelerate our growth through commercial execution of IGALMI. We are also on track for significant data readouts for our overall neuropsychiatric program that has potential to address an estimated 139 million agitation episodes in the U.S.[1-3*] We have two pivotal study readouts for BXCL501 expected in the second quarter of 2023. Lastly, we plan to advance our lead immuno-oncology program, BXCL701, into a Phase 2b registrational trial, pending further discussion with the FDA, in conjunction with exploring strategic options for our OnkosXcel subsidiary. These upcoming milestones, along with our strong financial foundation and late-stage programs, position BioXcel Therapeutics to deliver significant value to our shareholders while helping treat millions of patients."

Company Highlights

Neuroscience Franchise

IGALMI™ (dexmedetomidine) sublingual film

IGALMI is approved by the U.S. Food and Drug Administration (FDA) for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults.[4] *Up to an estimated 16 million institutional episodes occur annually within these two patient populations in the U.S.*[1-3*]

Commercial

- **Enhanced Market Access:** Continued to generate strong interest in IGALMI from key stakeholder groups to drive formulary access with initial 26-member field force.

- More than 600 hospital Pharmacy and Therapeutics (P&T) Committees decisions are scheduled, with over 65 total formulary wins to date.
- Targeting Integrated Delivery Network (IDN) universe of approximately 280,000 beds:
  - More than 70,000 (~25%) target IDN beds are scheduled to vote; secured formulary approval for ~7,000 (2%) target beds.
- Three Group Purchasing Organization (GPO) contracts in place covering nearly 50% of target beds; in active discussions with other leading GPOs.

- **Completed Deployment of IGALMI Institutional Sales Force:** Integrated commercial team covers majority of U.S. agitation market.
  - Expanded sales force to 70 representatives, extending coverage from 700 to more than 1,700 target hospitals.
  - Current target reach is more than 1,100 hospitals and over 7,000 unique health care professionals to influence formulary access.

- **Amplified Marketing Efforts:** Increased IGALMI awareness and education planned.
  - Launched new promotional campaign directed to health care providers (HCPs) through multiple channels.
  - Established large-scale peer speaker program designed to educate thousands of target HCPs in 1H 2023.
  - Planned promotional presence at leading national and regional conferences in 2023.

Medical Affairs

- **Increased Field Team Engagement:** Medical Science Liaison (MSL) and Medical Managed Care (MMC) teams continued to grow engagement with medical community and P&T committee members.
  - Increased HCP interactions by 50% from Q3 to Q4 2022 and observed growing interest of medical community in obtaining clinical information.
  - Established HCP relationships in top target academic medical centers.

- **Clinical Data Dissemination**:
  - Published three manuscripts and two letters to the editor in 2022; the first publication from SERENITY II pivotal trial, published in the *Journal of the American Medical Association (JAMA)*, has been viewed more than 32,000 times and cited by 15 other publications.
  - Preparing four new manuscripts and 19 conference abstract submissions for 2023.

Development Pipeline

BXCL501, a proprietary, sublingual film formulation of dexmedetomidine, has received Breakthrough Therapy and Fast Track designation for the acute treatment of agitation associated with dementia.

- **Alzheimer's Disease-related Agitation:** TRANQUILITY program is designed to evaluate BXCL501 for the acute treatment of Alzheimer's-related agitation, where up to 100 million agitation episodes are estimated to occur in the U.S. annually.[1*]
    - TRANQUILITY II: Trial is fully enrolled; nearing completion of three-month observation period in a few patients in assisted living facilities (ALFs) and residential settings.
        - Data cleaning and verification in progress.
        - Top-line data from pivotal trial expected in Q2 2023.
    - TRANQUILITY III: Continuing enrollment of patients with moderate to severe dementia in nursing homes.

- **Bipolar or Schizophrenia-related Agitation (At-Home Use)**: SERENITY III program is designed to evaluate BXCL501 for use at home, where up to 23 million agitation episodes are estimated to occur in the U.S. annually.[1-3*]

  SERENITY III consists of two parts:

    - Part 1: Assessing the efficacy and safety of 60mcg dose in acutely agitated patients with bipolar I or II disorder or schizophrenia in a supervised setting, similar to SERENITY I and II.
        - More than 90% of patients enrolled and complete enrollment is imminent.
        - Top-line efficacy data from pivotal trial expected in Q2 2023.
    - Part 2: Evaluating the safety of self-administration of 60mcg dose at-home.
        - Expect to initiate trial in Q2 2023.

- **Adjunctive Treatment for Major Depressive Disorder (MDD) for At-Home Use:** Phase 1b Multiple Ascending Dose (MAD) trial is designed to test safety and tolerability of daily dosing of BXCL501 to inform proof-of-concept (POC) trial dose selection in combination with selective serotonin - or serotonin-norepinephrine reuptake inhibitors (SSRIs or SNRIs, respectively) in MDD patients. Over 300 million antidepressant prescriptions are filled annually in the U.S.,[5*] and current treatments are limited by slow onset of action and incomplete responses.
    - Enrollment has been completed; cohorts have received either daily or twice-daily dosing regimens for seven days, including a final cohort in combination with an SNRI.
    - Data cleaning and verification in progress.
    - Top-line results are expected in Q2 2023.

Research and Development Pipeline

BXCL502: Novel serotonergic receptor antagonist being developed for chronic treatment of agitation in patients with dementia and other related neuro-psychiatric conditions.

- Protype formulation has been completed.
- Undergoing Investigational New Drug application-enabling studies.
- Development path leverages efficacy and safety data from prior Phase 3 pivotal studies conducted by other pharma companies.

Emerging Pipeline: Leveraging our proprietary AI platform and deep multidisciplinary neuroscience and development expertise to identify novel pipeline candidates for neuropsychiatric disorders and neuro-rare diseases.

- Large language models, knowledge graphs, deep learning and machine learning methodologies centered around neuro-circuitry and receptor targets that modulate them.
- This strategy has enabled discovery of numerous promising product concepts that have been rank-ordered using an index for transformative care and commercial opportunity.
- Company is prioritizing these opportunities to select development candidates.

OnkosXcel Therapeutics

OnkosXcel Therapeutics is a subsidiary of BioXcel Therapeutics focused on the sustained growth of the Company's immuno-oncology (I-O) franchise, including BXCL701, its most advanced I-O program. BXCL701 is an investigational, oral innate immune activator in development for the treatment of aggressive forms of prostate cancer and other solid and liquid tumors.

- **Small Cell Neuroendocrine Metastatic Castration-Resistant Prostate Cancer (SCNC) Program:** Presented positive Phase 2a efficacy data for BXCL701 in combination with KEYTRUDA® (pembrolizumab) at the 2023 ASCO GU Cancers Symposium, demonstrating clinical proof-of-concept. In 2023, there will be an estimated 288,300[6] new prostate cancer patients in the United States, with approximately 11,000 patients[7] progressing to SCNC.
    - BXCL701 has demonstrated activity in two prostate cancer subtypes ("cold" tumors).
        - Data from the SCNC cohort showed response rate, duration of response, and safety data consistent with previously presented data from the adenocarcinoma cohort.
    - BXCL701 in combination with KEYTRUDA demonstrated manageable adverse events (AEs) with no evidence of potentiation of immune-related AEs.
    - Planned Phase 2b potential pivotal study for BXCL701 monotherapy and in combination with KEYTRUDA in SCNC expected to initiate in 2H 2023, subject to further discussions with FDA.
    - Expect to initiate Phase 1b/2 trial in small cell lung cancer (SCLC) in 2H 2023.

- **Predictive Biomarker for BXCL701:** DPP9 overexpression was identified as a potential actionable biomarker for BXCL701 response.

- **Hosted BXCL701 Key Opinion Leader (KOL) Day:** Esteemed oncology experts highlighted the development landscape, challenges with current immunotherapy in prostate cancer, BXCL701 mechanism of action, and positive results from Phase 2 trial of BXCL701 in rare forms of prostate cancer.
    - Planning to pursue additional indications in partnership with Georgetown Lombardi Cancer Center and Dana-Farber Cancer Institute in pancreatic cancer and AML, respectively.

- **Strategic Advancements:** Actively evaluating strategic options for OnkosXcel Therapeutics, including potential partnering or third-party investments.

Corporate Updates

Patent Portfolio: The company is developing a broad global intellectual property portfolio, with over 100 patent applications in prosecution and multiple patents issued as of January 31, 2023.

- Neuroscience Franchise (BXCL501 and pipeline): Company's patent portfolio, includes five issued U.S. patents, with four listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), as well as three patents from Japan and four patents from other countries. Additionally, the portfolio has 13 utility patent applications and four provisional applications in the U.S. and 87 utility patent applications in other countries, as well as four Patent Cooperation Treaty (PCT) applications not yet in the national phase.

- Immuno-oncology Franchise (BXCL701 and pipeline): Company's patent portfolio, includes one issued patent in the U.S., one in Japan, and eight in other countries, as well as five provisional applications and seven utility patent applications in the U.S., including one with a Notice of Allowance, and 35 utility patent applications in other countries.

Fourth Quarter and Full Year 2022 Financial Results

Net Revenue: Net revenue was approximately $238,000 for the quarter and $375,000 for the full year 2022, which resulted from early product trials and reflects limited market access. Due to the Company's direct shipping model to hospitals, wholesaler stocking was neither expected nor occurred.

Research and Development (R&D) Expenses: R&D expenses were $32.5 million for the fourth quarter of 2022, compared to $12.5 million for the same period in 2021.

R&D expenses were $91.2 million for the full year 2022, compared to $52.7 million for the same period in 2021. The increased expenses for both the fourth quarter and the full year were primarily attributable to an increase in clinical trial costs related to multiple major pivotal BXCL501 clinical programs.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses were $20.7 million for the fourth quarter of 2022, as compared to $13.6 million for the same period in 2021.

SG&A expenses were $68.8 million for the full year 2022, as compared to $54.2 million for 2021. The increased costs for both the fourth quarter and full year were primarily due to personnel and costs related to the launch of IGALMI in the U.S.

Net Loss: BioXcel Therapeutics had a net loss of $54.8 million for the fourth quarter of 2022, compared to a net loss of $26.1 million for the same period in 2021. For the full year, BioXcel Therapeutics reported a net loss of $165.8 million, compared to a net loss of $106.9 million for the same period in 2021. The loss for the year includes approximately $17.3 million in non-cash stock-based compensation. Total cash expenditures for 2022 totaled approximately $135.3 million.

Cash and cash equivalents totaled $193.7 million at December 31, 2022, compared to $233.0 million at December 31, 2021. To date in the first quarter of 2023, the Company utilized its existing at-the-market equity facility and received net proceeds of approximately $24 million.

The Company believes that full execution of our strategic financing with Oaktree and Qatar Investment Authority would result in a cash runway into 2025 for the Company.

Anticipated Milestones

- Clinical Trial Readouts
  - Top-line data from pivotal TRANQUILITY II trial in Q2 2023
  - Top-line efficacy data from pivotal SERENITY III trial in Q2 2023
  - Top-line results from Phase 1b MAD trial for MDD program in Q2 2023
- Clinical Trial Initiations
  - Initiate SERENITY III Part 2 in Q2 2023
  - Initiate Phase 2b potential pivotal study of BXCL701 in SCNC in 2H 2023

Conference Call

BioXcel Therapeutics will host a conference call and webcast at 8:30 a.m. ET on March 9 to discuss its fourth quarter and full-year 2022 financial results and provide an update on recent operational highlights. To access the call, please dial 877-407-5795 (domestic) and 201-689-8722 (international). A live webcast will be available on the Investors section of the corporate website, bioxceltherapeutics.com, and a replay will be available through June 9, 2023.

BioXcel Therapeutics may use its website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investors sections of its website at www.bioxceltherapeutics.com. In addition, you may automatically receive email alerts and other information about the Company when you enroll your email address by visiting the “Email Alerts” option under the News/Events menu of the Investors & Media section of its website.

About IGALMI™ (dexmedetomidine) sublingual film

INDICATION

IGALMI is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. Limitations of Use: The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose.

IMPORTANT SAFETY INFORMATION

IGALMI can cause serious side effects, including:

- Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. IGALMI is taken under the supervision of a healthcare provider who will monitor vital signs (like blood pressure and heart rate) and alertness after IGALMI is administered to help prevent falling or fainting. Patients should be adequately hydrated and sit or lie down after taking IGALMI and instructed to tell their healthcare provider if they feel dizzy, lightheaded, or faint.

- Heart rhythm changes (QT interval prolongation). IGALMI should not be given to patients with an abnormal heart rhythm, a history of an irregular heartbeat, slow heart rate, low potassium, low magnesium, or taking other drugs that could affect heart rhythm. Taking IGALMI with a history of abnormal heart rhythm can increase the risk of torsades de pointes and sudden death. Patients should be instructed to tell their healthcare provider immediately if they feel faint or have heart palpitations.
- Sleepiness/drowsiness. Patients should not perform activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours after taking IGALMI.
- Withdrawal reactions, tolerance, and decreased response/efficacy. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence, withdrawal symptoms (e.g., nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.

The most common side effects of IGALMI in clinical studies were sleepiness or drowsiness, a prickling or tingling sensation or numbness of the mouth, dizziness, dry mouth, low blood pressure, and low blood pressure upon standing.

These are not all the possible side effects of IGALMI. Patients should speak with their healthcare provider for medical advice about side effects.

Patients should tell their healthcare provider about their medical history, including if they suffer from any known heart problems, low potassium, low magnesium, low blood pressure, low heart rate, diabetes, high blood pressure, history of fainting, or liver impairment. They should also tell their healthcare provider if they are pregnant or breastfeeding or take any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Patients should especially tell their healthcare provider if they take any drugs that lower blood pressure, change heart rate, or take anesthetics, sedatives, hypnotics, and opioids.

Everyone is encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com.

Please see full Prescribing Information.

About BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. is a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology. The Company's drug re-innovation approach leverages existing approved drugs and/or clinically validated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indices. The Company's commercial product, IGALMI™ (developed as BXCL501), is a proprietary, sublingual film formulation of dexmedetomidine approved for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. The safety and effectiveness of IGALMI has not been established beyond 24 hours from the first dose. For more information, please visit IGALMIhcp.com and also see the IGALMI full Prescribing Information. BXCL501 is under evaluation for at-home use for the acute treatment of agitation in bipolar and schizophrenia patients, for acute treatment of agitation associated with probable Alzheimer's disease and as an adjunctive treatment for major depressive disorder. The safety and efficacy of BXCL501 for these uses have not been established. The Company is also developing BXCL502 as a potential therapy for chronic agitation in dementia. Under its subsidiary, OnkosXcel Therapeutics, the Company is developing BXCL701, an investigational, oral systemic innate immune activator for the treatment of aggressive forms of prostate cancer and other solid and liquid tumors. The safety and efficacy of BXCL502 and BXCL701 have not been established. For more information, please visit bioxceltherapeutics.com.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the Company's expected timing of, and data results from, trials and clinical studies involving its product candidates; its ongoing marketing, commercialization and expansion efforts, plan and strategy for IGALMI; strategic options for OnkosXcel; the Company's participation in upcoming events and presentations; and the Company's future financial and operational results, including future revenue growth. The words "anticipate," "believe," "can," "continue," "could," "designed," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon the Company's current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; its significant indebtedness and other contractual obligations; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of IGALMITM, BXCL501, BXCL502 and BXCL701 and other product candidates; its lack of experience in marketing and selling drug products; the risk that IGALMI or the Company's product candidates may not be accepted by physicians or the medical community in general; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; undesirable side effects caused by the Company's product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; risks associated with the increased scrutiny relating to environmental, social and governance (ESG) matters; its ability to commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022, as such factors may be updated from time to time in its other filings with the SEC, including without limitation, its Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which are accessible on the SEC's website at www.sec.gov. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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Source: BioXcel Therapeutics, Inc.

References and Notes

Prevalence estimates show prominent variability and gradients

1. Wu EQ, Shi L, Birnbaum H, et al. Annual prevalence of diagnosed schizophrenia in the USA: a claims data analysis approach. Psychol Med. 2006;36(11):1535-1540.
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BioXcel Therapeutics, Inc.
Statements of operations
(in thousands, except per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Revenues	$ 238	$ -	$ 375	$ -
Operating expenses				
Cost of goods sold	$ 9	$ -	$ 20	$ -
Research and development	32,459	12,525	91,239	52,708
Selling, general and administrative	20,664	13,606	68,761	54,227
Total operating expenses	$ 53,132	$ 26,131	$ 160,020	$ 106,935
Loss from operations	$ (52,894)	$ (26,131)	$ (159,645)	$ (106,935)
Other expense (income)				
Interest expense	2,921	6	8,213	40
Interest income	(1,487)	(12)	(2,528)	(44)
Other (income) expense, net	480	-	427	-
Net loss and comprehensive loss	$ (54,808)	$ (26,125)	$ (165,757)	$ (106,931)
Net loss per share - basic and diluted	$ (1.95)	$ (0.93)	$ (5.92)	$ (4.05)
Weighted average shares outstanding - basic and diluted	28,068	27,980	28,015	26,373

Condensed Balance Sheets
(in thousands)

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 193,725	$ 232,968
Working capital	$ 169,970	$ 220,145
Total assets	$ 205,853	$ 239,439
Long-term liabilities	$ 96,180	$ 1,105
Total liabilities	$ 129,078	$ 17,772
Total stockholders' equity	$ 76,775	$ 221,667